

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

)	
IN RE PHARMACEUTICAL INDUSTRY)	MDL No.1456
AVERAGE WHOLESAL PRICE)	
LITIGATION)	
)	Master File No. 01-CV-12257-PBS
)	Subcategory Case No. 06-11337-PBS
)	
THIS DOCUMENT RELATES TO:)	Judge Patti B. Saris
<i>United States of America ex rel. Ven-A-Care of</i>)	
<i>the Florida Keys, Inc., et al. v. Boehringer</i>)	
<i>Ingelheim Corporation, et al., Civil Action No.</i>)	Magistrate Judge Marianne B. Bowler
07-10248-PBS)	

**BOEHRINGER INGELHEIM CORPORATION AND BOEHRINGER INGELHEIM
PHARMACEUTICALS, INC.'S REPLY TO THE UNITED STATES' RESPONSE TO
CORRECTED BOEHRINGER INGELHEIM CORPORATION AND BOEHRINGER
INGELHEIM PHARMACEUTICALS, INC. LOCAL RULE 56.1 STATEMENT OF
UNDISPUTED MATERIAL FACTS IN SUPPORT OF THEIR MOTION FOR
SUMMARY JUDGMENT**

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PRELIMINARY STATEMENT

Pursuant to Local Rule 56.1, Boehringer Ingelheim Corporation (“BIC”) and Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) submit this Reply to the United States’ Response to Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc. Local Rule 56.1 Statement of Undisputed Material Facts In Support of Their Motion for Summary Judgment. Copies of all referenced documents are attached as tabs to the contemporaneously-filed Declaration of John W. Reale in support of this Reply Statement of Fact or were previously attached to the Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc. Local Rule 56.1 Statement of Undisputed Material Facts In Support of Their Motion for Summary Judgment filed June 29, 2009 (with corrections filed June 29, 2009).

If a response asserted by the United States is undisputed by BIC and BIPI, it is undisputed solely for the purposes of BIC and BIPI’s Motion for Summary Judgment, and BIC and BIPI reserve the right to dispute any statement in future proceedings. To the extent that any of the United States’ responses contain alleged facts that are immaterial, not properly supported by the record, argumentative, or conclusory assertions, such statements should be rejected under Local Rule 56.1.

I. BIC, BIPI And Roxane Were Separate Legal Entities With Distinct Business Purposes

1. Boehringer Ingelheim Corporation (“BIC”) is incorporated in Nevada and has its principal place of business in Ridgefield, Connecticut. BIC serves as the parent company of Roxane, BIPI and several other U.S. subsidiaries. (United States’ First Amended Complaint ¶ 13 (“First Am. Comp.”); Tab 15, McIntyre Dep. 22-23; Tab 32, RLI-ORG00000016 (Jan. 1998 Organization Chart); Tab 33, RLI-ORG00000023 (Jan. 2000 Organization Chart))

United States’ Response: Undisputed. Further answering, BIC and its subsidiaries are part of the Boehringer Ingelheim worldwide group of companies which, during the relevant time frame, constituted the largest privately held pharmaceutical company in the world. (2/28/2009 Declaration of James J. Fauci Submitting Exhibits in Response to Corrected Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceutical Inc. Local Rule 56.1 Statement of Undisputed Material Facts In Support of Their Motion for Summary Judgment (hereinafter, “BIC/BIPI Fauci”) Exhibit 1). Roxane press releases identified the company as part of the “Boehringer Ingelheim worldwide group

of companies” and described the “Boehringer Ingelheim group” as “one of the 20 leading pharmaceutical corporations in the world.” (BIC/BIPI Fauci Exhibit 2)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibits 1 and 2 include the referenced statements, but dispute that these statements are material to BIC and BIPI’s motion for summary judgment. *See* L.R. 56.1 (requiring parties at summary judgment to “include a concise statement of the *material* facts of record”) (emphasis added); *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005) (refusing to consider a summary judgment movant’s immaterial facts).¹

2. BIC is largely a holding company with very few employees. (Tab 24, Tetzner Dep. 64; Tab 15, McIntyre Dep. 22-23; Tab 2, 10/31/08 Berkle Dep. 29-30; Tab 32, RLI-ORG00000016 (Jan. 1998 Organization Chart; Tab 33, RLI-ORG00000023 (Jan. 2000 Organization Chart))

United States’ Response: Undisputed. Further answering, Roxane documents describe BIC as having “[l]imited corporate functions” and identify BIC’s subsidiary, Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), as the “Primary Operating Company” for Boehringer Ingelheim’s various United States businesses. (BIC/BIPI Fauci Exhibit 3, at RLI-AWP-00107354) Consistent with BIPI’s status as the primary operating company, “[h]idden’ corporate functions” for the Boehringer Ingelheim group of companies such as human resources, legal, information technology and finance and administration were located within BIPI. (*Id.*)

In 2003, Boehringer Ingelheim considered various options for restructuring its businesses in the United States. According to a September 2003 presentation regarding the “U.S. Business of Boehringer Ingelheim,” there was no requirement to maintain BIC as a holding company and “there [wa]s no significant business advantage to keeping BIC, as the ‘corporate veil’ would likely be

¹ Local Rule 56.1 and *St. Paul Fire & Marine Ins. Co. v. Birch, Stewart, Kolasch & Birch, LLP*, 379 F. Supp. 2d 183, 186 n.1 (D. Mass. 2005), support the proposition that the Government’s immaterial facts should not be considered for purposes of BIC and BIPI’s summary judgment motion. This authority applies to, and BIC and BIPI hereby incorporate it into, all instances in which BIC and BIPI object to the Government’s alleged facts on grounds that the facts are not material to their statement of fact or Motion for Summary Judgment.

pierced in case of any litigation.” (*Id.* at RLI-AWP-00107358; *see also* BIC/BIPI Fauci Exhibit 4, at RLI-AWP-00114116)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

The Government’s additional facts and statements do not controvert, and are immaterial to, BIC and BIPI’s statement of fact.

BIC and BIPI dispute that the 2003 presentation is material, relevant, or admissible. BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 3 contains the quoted language, but the presentation cited therein is a draft; there is no indication that a BIC, BIPI or Roxane employee authored the document and no testimony that anyone at BIC, BIPI or Roxane knew, understood or agreed with statements contained in the draft presentation, as such statements are inconsistent with and contrary to the companies’ consistent efforts to maintain separate corporate formalities and separate financial records and operate independently. (*See* Corrected BIC and BIPI’s Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment filed June 29, 2009 (“BIC/BIPI SOF”) at ¶¶ 1-82)² Without foundation, this presentation is inadmissible and immaterial.

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 3 includes reference to “‘hidden’ functions” within BIPI such as human resources, legal, information technology, and finance and

² Any reference or citation to Corrected BIC and BIPI’s Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment is intended to incorporate both the original statement of fact and BIC and BIPI’s reply for that statement of fact.

accounting, but dispute that the fact that “the Boehringer Ingelheim group of companies” share such services is material to their motion for summary judgment. Professor Jonathan Macey testified that it is common for holding companies to provide shared services. (BIC/BIPI SOF at ¶ 89; Tab 98, 5/19/09 Macey Dep. 68-69; Tab 99, 5/20/09 Macey Dep. 359-60) In addition, Roxane was charged back and paid for the value of the shared services it used. (BIC/BIPI SOF at ¶ 49)

Further, BIC and BIPI dispute that any “human resources, legal, information technology and finance and administration” departments within BIPI provided support for Roxane for the entire relevant timeframe. Rather, at various points in time, Roxane employed individuals in its own Human Resources, Information Technology, and Finance Departments. (Tab 62, Roxane Organigram; Tab 112, Roxane Human Resources Organization Chart; Tab 113, Roxane Information Technology Organization Chart; Tab 114, Roxane Information Technology Organization Chart; Tab 115, Roxane Organization Chart; Tab 116, Roxane Finance Organization Chart; *see also* Tab 89, 1/27/05 Berkle Dep. 151-52; Tab 103, 9/20/05 Paoletti Dep. 141)

3. BIC has never owned, manufactured, marketed, or sold any pharmaceutical products and has no active business of its own. (Tab 15, McIntyre Dep. 22-23; Tab 14, 5/31/07 Marsh Dep. 21)

United States’ Response: Undisputed. (*See supra* United States’ Response to Paragraph 2)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI incorporate their Reply to ¶ 2.

4. BIC has its own Board of Directors and officers. (Tab 2, 10/31/08 Berkle Dep. 325, 358-362)

United States' Response: The United States does not dispute that BIC had a Board of Directors. Further answering, from 1996 through at least 2006, the composition of BIC and BIPI's respective Boards of Directors was identical, except that Walter Poerschmann served only on BIC's board from 2004 through 2006. (BIC/BIPI Fauci Exhibit 5 (Roxane's Response to Interrogatory 1, at 3-6); *see also* BIC/BIPI Fauci Exhibit 6 (10/19/2004 Tetzner Dep.), at 61:15 - 61:25) In addition, the BIC and BIPI Boards of Directors held joint board meetings from 1996 through at least 2003. (*See, e.g.*, BIC/BIPI Fauci Exhibit 7; BIC/BIPI Fauci Exhibit 8; BIC/BIPI Fauci Exhibit 9; BIC/BIPI Fauci Exhibit 64) Roxane business regularly was discussed at BIC/BIPI Board meetings, and important decisions about Roxane's business were at times made at such meetings. (*See, e.g.*, BIC/BIPI Fauci Exhibit 8, at BICJURIS at 0176-77; BIC/BIPI Fauci Exhibit 9, at BICJURIS0193-94; *see also infra* United States' Response to Paragraph 27)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). To the extent the Government's response is anything other than an unqualified admission, BIC and BIPI object to the Government's response because it is not clear what material facts, if any, it is disputing. The Government's additional facts do not contradict BIC and BIPI's statement of fact and are immaterial to this fact and their motion for summary judgment.

BIC and BIPI dispute that "the composition of BIC and BIPI's respective Boards of Directors was identical, except that Walter Poerschmann served only on BIC's Board from 2004 through 2006," as Mr. Poerschmann served on BIC's Board from January 1, 2004 through 2006 and on BIPI's Board from January 1, 2004 through 2006. (BIC/BIPI Fauci Ex. 5, 11/14/08 Roxane's Responses and Objections to Plaintiffs' Second Interrogatories at 3-6) Further, that BIC's and BIPI's Boards were identical is immaterial to BIC and BIPI's motion for summary judgment as it is common and courts have found that it is completely appropriate for parent and subsidiary corporations to have overlapping and often identical directors: "it is entirely appropriate for directors of a parent corporation to serve as directors of its subsidiary, and that fact alone may not

serve to expose the parent corporation to liability for its subsidiary's acts." *U.S. v. Bestfoods*, 524 U.S. 51, 69 (1998) (citation and quotation marks omitted); *see also C.M. Corp. v. Oberer Dev. Co.*, 631 F.2d 536, 539 (7th Cir. 1980) (noting that overlap in officers and directors is insufficient to invoke the veil-piercing doctrine because it "exist[s] in most parent and subsidiary relationships.") (citation and quotation marks omitted).

Although immaterial for the same reasons, BIC and BIPI do not dispute that "the BIC and BIPI Boards of Directors held joint board meetings from 1996 through at least 2003." BIC and BIPI dispute any implication that all BIC and BIPI board meetings were jointly held, as BIC and BIPI held individual board meetings during this timeframe. (*See, e.g.*, Tab 117, Minutes of the March 1, 1996 Meeting of the BIPI Board of Directors at BOEH02605715; Tab 118, Minutes of the April 28, 1999 Meeting of the BIC Board of Directors at BICJURIS0208)

BIC and BIPI dispute that "Roxane business regularly was discussed at BIC/BIPI Board meetings, and important decisions about Roxane's business were at times made at such meetings." This fact is not supported by the Government's proffered evidence. First, the cited meeting minutes reflect that the BIC Board merely "recommended for approval" Roxane's "year end closing statements, including the Profit and Loss Statement and Balance Sheet as at December 31, 1999." (BIC/BIPI Fauci Ex. 8, 5/15/00 BIC/BIPI Board of Directors Meeting Minutes at BICJURIS0179) It was the Roxane Board of Directors, not the BIC Board of Directors, that ultimately approved the year-end statements through unanimous written consent. (Tab 42, Roxane Laboratories, Inc. Unanimous Written Consent of Directors at BOEH04600330) Moreover, this fact is immaterial to BIC and BIPI's motion as one would expect general subsidiary business updates to be discussed at a parent's board meeting. Additionally, BIC and BIPI incorporate their Reply to ¶ 27.

5. Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) is a wholly-owned subsidiary of BIC, and is also located in Ridgefield, Connecticut. It was incorporated under the laws of Delaware. (Tab 29, 5/11/07 Waterer Dep. 523; Tab 14, 5/31/07 Marsh Dep. at 21; First Am. Comp. ¶ 14) BIPI is in the business of marketing and selling brand-name, patent-protected pharmaceutical products. (Tab 2, 10/31/08 Berkle Dep. 29; Tab 15, McIntyre Dep. 21)

United States’ Response: Undisputed. Further answering, Boehringer Ingelheim employees at times referred to BIC and/or BIPI as “Connecticut” or the “Connecticut office.” (*See, e.g.*, BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 36:5 - 36:22; BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.), at 168:24 - 170:5; BIC/BIPI Fauci Exhibit 12 (12/4/2008 Sykora Dep.), at 95:8 - 96:21)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). The Government’s additional facts do not contradict BIC and BIPI’s statement of fact and are immaterial to their motion for summary judgment.

Although immaterial, BIC and BIPI dispute that “Boehringer Ingelheim employees at times referred to BIC and/or BIPI as ‘Connecticut’ or the ‘Connecticut office.’” This is not supported by the referenced testimony. The testimony cited by the Government is selective and incomplete; the deposition testimony in its entirety is the best evidence of its content. The Government’s proffered evidence shows only that BIC and BIPI’s offices were located in Connecticut. (*See* BIC/BIPI SOF at ¶¶ 1, 5) Mr. Russillo’s deposition testimony was as follows:

Q: Next to the date, it says Ridgefield, Connecticut. Which company was based in Ridgefield, Connecticut?

A: Ridgefield, Connecticut, to me meant BIPI.

Q: Did it also mean BIC?

A: It could have, yes.

(BIC/BIPI Fauci Ex. 10, 1/8/09 Russillo Dep. 36) Mr. Russillo also testified that when making marketing decisions on Roxane products, he did not normally require the approval of Werner Gerstenberg, President and COO of Roxane. (*Id.* at 28-29; BIC/BIPI SOF at ¶ 30) However, Mr. Russillo explained on several occasions that if he did consult Mr. Gerstenberg, who was located in Connecticut, regarding Roxane business, Mr. Gerstenberg “would have been acting as the president of Roxane.” (BIC/BIPI Fauci Ex. 10, 1/8/09 Russillo Dep. 98, 174-75; *see also* BIC/BIPI SOF at ¶¶ 60-62, 71)

Likewise, Ms. Waterer’s testimony explains only that Mr. Gerstenberg was Mr. Russillo’s boss and that Mr. Gerstenberg worked in Connecticut. (BIC/BIPI Fauci Ex. 11, 10/24/01 Waterer Dep. 168-70) Mr. Sykora’s testimony likewise merely establishes that “Boehringer Ingelheim is based in Connecticut” and that a reference to Connecticut would be either to “Boehringer Ingelheim” or “some individual from Boehringer Ingelheim located in Connecticut.” (BIC/BIPI Fauci Ex. 12, 12/4/08 Sykora Dep. 95-96)

6. BIPI has its own FDA labeler code that is assigned to the BIPI-labeled products it markets and sells. BIPI’s labeler code is 00597. (Tab 35, Food & Drug Administration National Drug Code Directory, *available at* <http://www.accessdata.fda.gov/scripts/cder/ndc/queryndcfn.cfm>)

United States’ Response: Undisputed.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

7. BIPI has its own marketing department and budget. (Tab 2, 10/31/08 Berkle Dep. 323- 24)

United States' Response: The United States does not dispute that BIPI had employees whose titles indicated they had marketing responsibilities, or that BIPI had a budget related to marketing activities. The United States disputes this paragraph to the extent it suggests that BIPI's marketing personnel did not participate in marketing decisions for Roxane's products, including for the Subject Drugs. Employees in BIPI's marketing department regularly participated in such decisions, including decisions to set inflated AWP's. Whether BIPI had "its own" marketing department and/or budget is immaterial to whether BIPI was involved in the conduct for which the United States is seeking damages.

Further answering, in or around 1994, Sheldon Berkle became an Executive Vice President of Marketing at BIPI and assumed "the newly created position 'Head of Business Unit Ethical Pharmaceuticals USA.'" (BIC/BIPI Fauci Exhibit 13; BIC/BIPI Fauci Exhibit 14) Although Mr. Berkle served on Roxane's Board of Directors, he never was an officer at Roxane and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18) Through at least 2000, the Business Unit Ethical Pharmaceuticals (sometimes referred to as the "Business Unit" or the "BU") included BIPI and Roxane's businesses, as well as the business of a third Boehringer Ingelheim entity, Ben Venue Laboratories. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 57:14 - 58:16; BIC/BIPI Fauci Exhibit 16, at BICJURIS0236; BIC/BIPI Fauci Exhibit 17, at RLI-AWP-00162483; BIC/BIPI Fauci Exhibit 18, at RLI-AWP-00161738) From at least 1994 through 2000, senior executives at Roxane, including Edward Tupa (Vice President, Sales and Marketing) and Frederick Duy (Vice President, Business Planning and Development), reported "functionally" to Mr. Berkle in his capacity as Head of the Business Unit. (BIC/BIPI Fauci Exhibit 13, at RLI-AWP-00161743; BIC/BIPI Fauci Exhibit 19 (11/10/2005 Tupa Dep.), at 52:6 - 52:20; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 48:19 - 51:4, 53:2 - 54:16; BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.), at 217:8 - 218:3 (noting that "Shelly Berkle, for a period of time, headed up the sales and marketing of both BIPI and Roxane")) According to Mr. Duy, if he was going to make a "significant move with respect to a drug," he needed to obtain Mr. Berkle's approval. (BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 53:2 - 54:16)

An October 23, 1998, Employee Bulletin announced several organizational changes designed to increase management of "the Business Unit as a unified and focused organization." (BIC/BIPI Fauci Exhibit 18) Although "separate legal entities" would be preserved for BIPI, Roxane and Ben Venue Labs, the 1998 changes were designed to achieve "much greater synergy across the entire Business Unit." The changes included, among other things, "increasing the degree of collaboration between the marketing of [Roxane] product lines and BIPI product lines," and creating a "unified pricing process for the Business Unit." (*Id.*, at RLI-AWP-00616739-40)

The extent of BIPI's participation in the marketing of Roxane's products can be seen in the launch of Roxane's ipratropium bromide (sometimes referred to as "IBUDV") product in June 1996. In or around September of that year, BIPI expected to lose patent exclusivity for its Atrovent Unit Dose Vial ("UDV") product. (BIC/BIPI Fauci Exhibit 21, at ROX-TX 01341) According to minutes from an October 5, 1995 meeting of the BIPI Board of Directors, BIPI pre-empted the possibility of generic competition "through *its* planned launch of a generic by [Roxane] prior to another generic's entry into the market." (BIC/BIPI Fauci Exhibit 22, at BOEH02605569 (emphasis supplied)) On October 26, 1995, David Townley (an employee at Boehringer Ingelheim's parent company in Germany) sent an email to senior officials in the Roxane and BIPI marketing departments (including Mr. Tupa and Mr. Berkle) regarding Unit Dose Vial strategy. (BIC/BIPI

Fauci Exhibit 23) Mr. Townley discussed various approaches to “defend against generic erosion of Atrovent from non-BI companies” and advised that:

This should be from a total USA perspective, *ie. BIPI and Roxane combined strategy*. For example how much Ipratropium UDV business can Roxane take from BIPI and how do we “shut out” other non-BI generics as far as possible.” What is likely to be the change in price levels? Does offering a bundle of UDV substances assist and by how much?

(*Id.*) (emphasis supplied)

On or about January 24, 1996, representatives of Roxane Laboratories (including Ed Tupa and consultant Mark Pope) met with representatives of BIPI to discuss the approaching launch of ipratropium bromide and to develop a “rudimentary strategy to achieve success within this market.” (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 109:15 - 111:16; BIC/BIPI Fauci Exhibit 24, at RLI-AWP-00299558) Minutes from this meeting were sent to Mr. Berkle. (*Id.*) The meeting included discussion of “Medicare reimbursement” and the pricing structures for Atrovent and ipratropium bromide including, specifically, that the AWP for ipratropium bromide was to be set at 10% below Atrovent’s AWP. (*Id.* at RLI-AWP-00299559-60) According to the meeting minutes:

It was Roxane’s understanding that BIPI will maintain their current price structure and allow business that is price sensitive to convert to the Roxane product. An agreement must be made and closure should be put on this issue as early as possible. It should be noted that the AWP for IBUDV will be 10% below Atrovent’s AWP at the time of launch, contract pricing still needs to be finalized but the estimated average selling price for 1996 is \$21.00.

(*Id.* at RLI-AWP-00299559-60) The AWP for ipratropium bromide ultimately was set at \$44.06, which was 10% below Atrovent’s AWP. (BIC/BIPI Fauci Exhibit 21, at ROX-TX 01344) According to the April 17, 1996 ipratropium bromide marketing plan, this type of price structure was used to create an attractive spread between WAC and AWP and thereby “entice” accounts to switch from the brand name to the generic product. (*Id.*) Mr. Tupa testified that he believed Mr. Berkle was involved in the decision to approve the ipratropium bromide marketing plan. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.), at 36:15 - 37:17)

Ipratropium bromide was launched in June 1996, several months prior to the expiration of patent exclusivity for Atrovent. The decision to launch ipratropium bromide preemptively allowed customers to “enjoy substantial profits” but “cost” the innovator company (*i.e.*, BIPI) “a lot of money,” due to sales migrating to Roxane instead of BIPI while BIPI still enjoyed patent protection. (BIC/BIPI Fauci Exhibit 26; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 147:19 - 148:7) Mr. Berkle testified that the decision to allow Roxane to launch ipratropium bromide preemptively had no long term strategic benefits to BIPI, but that the decision was beneficial to the “Boehringer family” of companies. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 119:6 - 120:20) Mr. Berkle also testified that Roxane and BIPI worked together “to try and maintain the Ipratropium business whether it be Atrovent or otherwise within the Boehringer family of companies.” (*Id.* at 91:16 - 92:13)

When Roxane had trouble supplying ipratropium bromide orders in late 1996, it filled such orders with Atrovent instead. (BIC/BIPI Fauci Exhibit 27) Although the average selling price for Atrovent was approximately \$35.00, Roxane obtained Atrovent and sold it to customers at the significantly reduced “generic price.” (*Id.*; BIC/BIPI Fauci Exhibit 26) Roxane expected that customers “who get their hands on Atrovent at the distressed price” would use it for brand as well as generic sales, and that customers would use the brand as a “hook” to increase sales. (BIC/BIPI Fauci Exhibit 27, at RLI-AWP-00431168-69)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIPI’s separate marketing department and budget are material because they go directly to the corporate separateness of BIPI and Roxane, and, in particular, the separate marketing functions that BIPI and Roxane each had for their drugs. The Government’s additional alleged facts do not controvert BIC and BIPI’s statement of fact and do not create a disputed issue of fact material to their motion for summary judgment. In addition to the reasons stated below, BIC disputes that the additional facts alleged by the Government in its response are material to its motion for summary judgment because they relate solely to BIPI.

BIC and BIPI dispute that BIPI’s marketing personnel “regularly participated” in the marketing of Roxane’s drugs, including decisions to set allegedly inflated AWP’s, as the Government provides no basis for this alleged fact and it is not supported by proper citations to the record. *See O’Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006). (disregarding “purported statements of ‘fact’ not properly supported by citations to the record” in summary judgment pleadings as required by Local Rule 56.1). BIC and BIPI further dispute that AWP’s for Roxane’s drugs were “inflated.” (*See* Roxane’s Response to the United States’ Local Rule 56.1 Statement of Undisputed Material Facts as to the Roxane Defendants filed August 28, 2009 (“Roxane Resp. to US

Roxane SOF”) at ¶¶ 82, 137-38; The Roxane Defendants’ Reply to the United States’ Response to the Roxane Defendants’ Statement of Undisputed Material Facts in Support of Motion for Partial Summary Judgment and Statement of Additional Undisputed Facts in Support of Motion for Partial Summary Judgment filed August 28, 2009 (“Roxane Reply to SOF”) at ¶¶ 99-102)

BIC and BIPI do not dispute that a functional Business Unit concept was put into place in or around 1994 or that Mr. Berkle became “Head of Business Unit Ethical Pharmaceuticals USA.” Further, in addition to becoming an Executive Vice President of Marketing at BIPI at that time, Mr. Berkle also became a Vice President at BIC. (BIC/BIPI Fauci Ex. 13, 8/25/94 BIPI/BIC Employee Bulletin re Structural and Personnel Changes at 2) Mr. Berkle was also a Roxane director from 1996-2002. (BIC/BIPI Fauci Ex. 5, 11/14/08 Roxane’s Responses and Objection to Plaintiffs’ Second Interrogatories at 4) Thus, as is common, Mr. Berkle wore several different “hats” at BIC and its subsidiaries. BIC and BIPI do not dispute that Mr. Berkle was not an officer of Roxane or paid by Roxane. This is immaterial, however, as Mr. Berkle was a Roxane director and was given a specific management oversight role for Roxane as Head of the Business Unit, and therefore any material actions Mr. Berkle took with regard to Roxane were taken on behalf of Roxane pursuant to those positions. (BIC/BIPI SOF at ¶ 91) Further, Professor Macey testified that in situations where employees serve dual roles at two companies, the “overwhelming business practice in the United States is to have people receive a single paycheck.” (BIC/BIPI SOF and Reply to SOF ¶ 93)

BIC and BIPI do not dispute that certain evidence indicates that the Business Unit generally included BIPI, Roxane and later, Ben Venue. However, the testimony of Boehringer witnesses confirms a general understanding that the Business Unit was comprised only of BIPI’s brand drug business and Roxane’s brand and branded generic business. (Tab 106, 1/8/09 Russillo Dep. 35, 37-38, 45-46 (“From my recollection, the business unit Ethical Pharmaceuticals was the unit that

oversaw the brand business”; the multisource business was not included); Tab 97, 12/3/04 King Dep. 23-24 (business unit only encompassed the brand part of the business)) Regardless, this fact is immaterial for the reasons stated below.

BIC and BIPI do not dispute that for certain periods of time two of Roxane’s personnel, Mr. Tupa and Mr. Duy, reported “functionally” to Mr. Berkle, wherein there was a “dotted line” reporting relationship to Mr. Berkle, who would provide “functional advice” to Roxane. As the Government’s own evidence indicates, however, Mr. Tupa and Mr. Duy continued to have a direct reporting relationship to the President of Roxane. (BIC/BIPI Fauci Ex. 14, BIPI/BIC Job Description re Vice President at RLI-TX 62839; BIC/BIPI Fauci Ex. 19, 11/10/05 Tupa Dep. 52-53; BIC/BIPI Fauci Ex. 20, 12/16/08 Duy Dep. 54; *see also* Tab 90, 10/31/08 Berkle Dep. 50-51) Moreover, when Mr. Russillo took over Mr. Tupa’s role with regard to multisource products, he testified that he did not report to Mr. Berkle, but only to Mr. Gerstenberg, who was the President of Roxane at the time. (Tab 106, 1/8/09 Russillo Dep. 29; BIC/BIPI SOF at ¶ 30) BIC and BIPI do not dispute that Mr. Duy testified as described or that the October 23, 1998 Bulletin contains the quoted language. The Government’s quotations, however, are selective, incomplete and misleading; the document in its entirety is the best evidence of its contents. In addition, these facts are immaterial for the reasons stated below.

BIC and BIPI dispute that the Government’s alleged facts relating to the Business Unit and Mr. Berkle’s position are material to their motion for summary judgment or the Government’s direct liability or veil-piercing claims against them as the facts do not demonstrate that BIC or BIPI had any direct involvement in setting or reporting AWP’s for any Subject Drug and do not demonstrate lack of corporate separateness between BIPI and Roxane or that BIPI pervasively controlled Roxane’s operations. The undisputed testimony of Mr. Berkle is that as Head of the Business Unit

he only had high-level, strategic oversight over Roxane's sales and marketing business and was not involved in its day to day operations. (Tab 90, 10/31/08 Berkle Dep. 38 (Berkle only had "strategic oversight of Roxane, [] Roxane had its own management team and it was responsible for the annual budgets, marketing plans, day-to-day operations."); Tab 89, 1/27/05 Berkle Dep. 23-24; Tab 90, 10/31/08 Berkle Dep. 50-51, 76, 125, 186-87 ("I really had a strategic involvement with Roxane, not an operational day-to-day involvement"); BIC/BIPI SOF at ¶¶ 14, 51, 56) Mr. Tupa, a Roxane employee, continued to lead Roxane's marketing and sales department and handle the day-to-day operational marketing and sales activities. (Tab 61, Berkle Ex. 5, 5/3/96 Reorganization Announcement ("The Roxane Marketing & Sales Department will be led by Mr. Edward Tupa, who currently has this responsibility."); Tab 90, 10/31/08 Berkle Dep. 50-51) Moreover, as discussed above, any involvement Mr. Berkle did have in any material sales and marketing decisions for Roxane products was done on behalf of Roxane pursuant to his roles as director of Roxane and Head of the Business Unit. There is no basis to impute his actions to BIPI. (BIC/BIPI SOF at ¶ 91)

In addition, although certain parts of Roxane's and BIPI's businesses were part of the same business unit for internal functional purposes, the record is clear that Roxane and BIPI remained two separate legal entities and that their separate corporate identities were respected. For example, Roxane and BIPI maintained separate Boards of Directors, offices, employees, products, financial statements and accounting records, and marketing and sales departments. (Tab 63, Berkle Ex. 27 at 2, 10/23/98 Reorganization Memo ("We will continue to maintain separate legal entities for BIPI, RLI and BVL"); BIC/BIPI SOF at ¶¶ 4-9, 15, 21, 31, 52) Indeed, in explaining the organizational changes announced in 1998 to increase the "synergy" and "degree of collaboration" for BIPI's and Roxane's brand and branded generic product lines that the Government references above, Mr. Berkle explained that the goal was to "do away with wasted effort," to avoid "duplication," and

“to amalgamate services that were common to the various companies,” but that “Roxane and BIPI were always separate entities, they were always separate management within each entity and the day-to-day business for each of those entities was done within that entity.” (Tab 90, 10/31/08 Berkle Dep. 186-87) This type of functional coordination between affiliates to achieve efficiencies is common practice. (Tab 98, 5/19/09 Macey Dep. 72-77)

BIC and BIPI dispute that “the extent of BIPI’s participation in the marketing of Roxane’s products can be seen in the launch of Roxane’s ipratropium bromide” product in 1996, as the Government’s proffered evidence does not support this alleged fact. The launch of ipratropium bromide was a unique situation in which Roxane was launching the generic version of the BIPI-branded product, Atrovent, and therefore it was only natural that there would be a certain amount of discussion and coordination between the affiliated companies. (Tab 89, 1/27/05 Berkle Dep. 45, 72-73 (“in the case of ipratropium which was a unique case because the branded product was marketed by [BIPI] . . . [t]here was a sharing of information”); 28 ([Berkle] would be involved in discussions because, again, we marketed Atrovent, the brand. And Roxane was a sister company. And, therefore, there was cross fertilization of general information about our experiences with Atrovent.”)) In addition, this unique circumstance explains why there were high level communications from parent company employees, such as that reflected in BIC/BIPI Fauci Exhibit 23, the e-mail from Mr. Townley. With regard to BIC/BIPI Fauci Exhibit 23, Mr. Berkle testified that there was no “combined strategy” for ipratropium bromide and that Mr. Townley was “at a lower level in parent company, who has no directive or responsibility to tell how to establish strategies. . . . [A]nd the reason he wrote to both Ed and to Ian was recognizing that they each had to provide input” from a BIPI and from a Roxane point of view. (Tab 89, 1/27/05 Berkle Dep. 81-82) This type of situation, however, did not occur with any other Subject Drug or in any other

timeframe. Thus, it is misleading for the Government to imply the evidence surrounding the launch of ipratropium bromide reflects the routine interaction between BIPI and Roxane on a more widespread or ongoing basis. Moreover, the high-level interaction in this exceptional circumstance is immaterial to BIC and BIPI's motion for summary judgment because it does not demonstrate that BIC or BIPI had any direct involvement in setting or reporting AWP's for any Subject Drug and does not demonstrate lack of corporate separateness between BIPI and Roxane or that BIPI pervasively controlled Roxane's operations.

BIC and BIPI do not dispute that BIPI and Roxane employees met and discussed the launch of Roxane's ipratropium bromide at a meeting that appears to have occurred in January 1996 or that BIC/BIPI Fauci Exhibit 24 contains the language quoted by the Government. The Government's quotations, however, are selective, incomplete and misleading; the entirety of the document is the best evidence of its contents. BIC and BIPI dispute that this meeting is material to their motion for summary judgment. There is no evidence that there was more than one meeting between BIPI and Roxane employees, or that the meeting participants discussed anything beyond a general ipratropium bromide market overview. (Tab 110, 10/18/05 Via Dep. 66; BIC/BIPI Fauci Ex. 24, Ipratropium Bromide UDV Generic Launch Meeting Summary) Further, the meeting minutes do not support that BIPI personnel had any involvement or provided input into the decision to set the launch AWP for ipratropium bromide at 10% less than the AWP for Atrovent. Indeed, as the language quoted by the Government reflects, the minutes merely state that "[i]t should be noted that the AWP for IBUDV will be 10% below Atrovent's AWP at the time of launch," implying this had already been determined by Roxane. (BIC/BIPI Fauci Ex. 24, Ipratropium Bromide UDV Generic Launch Meeting Summary at ROX 04291-92) Indeed, the AWP for ipratropium bromide was set at 10% below the brand in accordance with "the traditional parameters of a generic product" and standard

practice at Roxane, and thus there was little to decide or discuss regarding ipratropium bromide's AWP, especially with a brand drug company like BIPI. (See BIC/BIPI Fauci Ex. 21, T. Via's 4/17/96 Ipratropium Inhalation Solution UDV Marketing Plan at 5; Corrected Roxane Local Rule 56.1 Statement of Undisputed Material Facts in Support of Motion for Summary Judgment filed June 29, 2009 ("Roxane SOF") at ¶ 99)³ The Government's reference to a discussion regarding "Medicare reimbursement" at this meeting is taken out of context and is not material to BIC and BIPI's motion. BIC and BIPI incorporate Roxane's Responses to ¶ 46 of the US' SOF re Roxane.

Nor is Mr. Tupa's testimony that he "believed" Mr. Berkle was involved in approving the ipratropium bromide market plan material to BIC and BIPI's motion for summary judgment in light of other evidence. First, Mr. Tupa's full testimony is that "the president of the company would be involved, and I – I – I *believe* Mr. Berkle had been involved as well." (BIC/BIPI Fauci Ex. 25, 1/31/03 Tupa Dep. 37 (emphasis added)) Mr. Berkle, however, testified that he did not recall approving the marketing plan for ipratropium bromide and that "I would not have had access necessarily to the detailed marketing plan. I was concerned with the overall forecasts and general strategies, but not in the nitty-gritty of the marketing plan. Mr. Wojta [the President and COO of Roxane at the time] really had the responsibility and the authority to approve that." (Tab 89, 1/27/05 Berkle Dep. 107) Further, the AWP launch figure was only one small piece of the overall marketing plan prepared by Mr. Via, and Mr. Berkle unequivocally testified that "anything to do with the establishment of pricing [for ipratropium bromide] was decided within the Roxane organization, had to be approved by the CEO of the Roxane – or the president of the Roxane organization." (*Id.* at 72-73; *see also* Tab 90, 10/31/08 Berkle Dep. 77-78 ("I was not involved in the marketing or pricing of

³ Any reference or citation to Corrected Roxane Local Rule 56.1 Statement of Undisputed Material Facts in Support of Motion for Summary Judgment is intended to incorporate both the original statement of fact and Roxane's reply for that statement of fact.

Ipratropium Bromide.”)) Thus, Mr. Tupa’s testimony does not create a genuine issue of fact regarding Mr. Berkle’s involvement in setting the AWP for ipratropium bromide.

BIC and BIPI dispute that the “spread” between the WAC and AWP for ipratropium bromide is material to their motion for summary judgment and state that Roxane’s purpose in creating an AWP/WAC spread for ipratropium bromide was to “encourag[e] accounts to convert from the brand name to the generic product as quickly as possible” (BIC/BIPI Fauci Ex. 21, T. Via’s 4/17/96 Ipratropium Inhalation Solution UDV Marketing Plan at 5), a goal that CMS itself just recently stated justified AWP to acquisition costs spreads as high as 73%. (Tab 119, January 2008 OIG Report at 6 and pg. 1 of App. G) BIC and BIPI incorporate Roxane’s Responses to ¶ 51 of the US’ SOF re Roxane.

BIC and BIPI do not dispute that the documents and depositions cited in the sixth paragraph of the Government’s response contain the language quoted by the Government. The Government’s quotations, however, are selective and incomplete; the entirety of the document and depositions are the best evidence of their content. In addition, the fact that BIPI agreed to allow Roxane to launch its generic version of ipratropium bromide several months prior to BIPI’s patent on Atrovent expiring is immaterial to BIC and BIPI’s motion for summary judgment. First, BIPI faced inevitable competition from generic competition and had no option that would provide it with a long term benefit. (Tab 90, 10/31/08 Berkle Dep. 81-82) The fact that BIPI chose to give Roxane the right to preemptively launch its generic product, similar to an authorized generic, rather than a third party company, makes good business sense and is what would be expected among affiliated companies. Indeed, as Professor Macey pointed out, BIPI was receiving a royalty payment from Roxane on Roxane’s sales of generic ipratropium bromide and therefore it did have an incentive to allow Roxane to launch early in order to capture a greater share of the market. (Tab 98, 5/19/09 Macey

Dep. 103-104; BIC/BIPI SOF at ¶¶ 47-48) In addition, the fact that ipratropium bromide was launched preemptively is not material to the Government's direct liability claims against BIC or BIPI as it does not show any direct involvement by BIPI in setting or reporting AWP's for any Subject Drug.

BIC and BIPI dispute the statements in the last paragraph of the Government's response except that they do not dispute that BIC/BIPI Fauci Exhibit 27 contains the language quoted by the Government. The Government misrepresents what occurred in this situation. In or around October 1996, Roxane faced a supply shortage on its generic ipratropium. (BIC/BIPI Fauci Ex. 27, 10/20/96 Memo re Ipratropium Bromide Back-Order Management Plan at RLI-AWP 00431168) At the same time, BIPI had a significant amount of inventory that was "very near its dating cut-off" and that it had "no way to move [] without drastically impacting [its] brand sales for many months to come." (*Id.*) In order to resolve this "unique situation," it was decided that for a limited time BIPI would fill orders for generic ipratropium with Atrovent at the generic price. BIPI created new customer files for the orders, filled the orders and recorded the sale as a BIPI sale. (Tab 121, McIntyre Ex. 10, 10/23/96 Memo re Atrovent Solution Sales at ROX-TX 00707-709; Tab 122, McIntyre Ex. 12, E-mail chain re Ipratropium/Atrovent at 2) As described by the BIPI employee involved, "[t]his is a win-win-win situation. BIPI wins because we will move excess inventory at a reasonable price. Roxane wins because they will preserve their market presence created by their early entry into the market." (Tab 121, McIntyre Ex. 10, 10/23/96 Memo re Atrovent Solution Sales at ROX-TX 00707) This type of cooperation that benefits both companies is what you would expect to see from affiliated companies and therefore these facts are immaterial to BIC and BIPI's motion for summary judgment. In addition, this situation does not relate to AWP pricing or reporting and it is therefore immaterial to the Government's directly liability claims against BIC or BIPI.

8. BIPI has its own sales force that promotes BIPI products. (*Id.*)

United States' Response: The United States does not dispute that BIPI had sales personnel with responsibility for promoting BIPI products. The United States disputes this paragraph to the extent it suggests that Roxane and BIPI had separate sales forces, or that BIPI sales personnel did not promote Roxane's products. Whether BIPI had "its own" sales force is immaterial to whether BIPI was involved in the conduct for which the United States is seeking damages.

Further answering, BIPI sales personnel promoted Roxane's products, including the Subject Drugs. For example, on or about May 17, 1996, James King sent an email to the BIPI sales force announcing that Roxane's promotion of ipratropium bromide began on June 3 of that year, and advising sales personnel that "if Roxane's ipratropium bromide is sold, or if an Atrovent solution is sold, you get credit for it." (BIC/BIPI Fauci Exhibit 28; *see also* BIC/BIPI Fauci Exhibit 29) Beginning in at least 1998, Mr. King began supervising both the BIPI and "RLI branded" sales forces (with responsibility for selling Subject Drugs Roxicodone and Oramorph SR), and running a "sales training group" at Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 15:2 - 15:23, 25:15 - 26:8; BIC/BIPI Fauci Exhibit 18, at RLI-AWP- 00161739) Mr. King testified that although he supervised Roxane sales personnel, he was employed in the BIPI sales department for his entire career and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 11:13 - 12:4, 24:14 - 24:25)

In addition, from at least 1996 through approximately 2001, "National Accounts Managers" in the Business Unit's "Trade Relations Group" promoted both the Roxane and BIPI product lines to chain drug stores, wholesalers and large national buying groups. (*See, e.g.*, BIC/BIPI Fauci Exhibit 31) The National Account Managers promoted the Roxane and BIPI product lines to wholesalers and other important customers through at least 2001. (*See, e.g.*, BIC/BIPI Fauci Exhibit 35 (1/25/2005 Gordon Dep.), at 19:14 - 21:9; BIC/BIPI Fauci Exhibit 37 (12/2/2005 Doan Dep.), at 43:19 - 44:8; BIC/BIPI Fauci Exhibit 38 (11/22/2005 Tavolaro Dep.), at 57:17 - 59:1) Specifically, in or around 1996, Mr. Tupa hired Richard Feldman as Director, Trade Relations, with responsibility for promoting both the Roxane and BIPI product lines. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.), at 137:9-138:14; BIC/BIPI Fauci Exhibit 32 (noting that Mr. Tupa is "in the process of recruiting for the position of Director, Trade and Pharmacy Affairs which will focus greater attention on this critical aspect of both the BIPI and Roxane businesses"); BIC/BIPI Fauci Exhibit 33 (11/18/2005 Feldman Dep.), at 59:2 - 60:22) Mr. Feldman had responsibility for promoting Roxane and BIPI products until approximately 2001, when he began to promote only BIPI products. (BIC/BIPI Fauci Exhibit 34 (11/17/2004 Feldman Dep.), at 108:24 - 109:25) After 2001, it was decided that Roxane and BIPI should have their own Trade Relations groups, and the employees in the Trade Relations unit were split between Roxane and BIPI. (*See, e.g.*, BIC/BIPI Fauci Exhibit 35 (1/25/2005 Gordon Dep.), at 19:23 - 21:9)

Reporting to Mr. Feldman was Robert Sykora, who served as the director of approximately six to eight National Account Managers. (BIC/BIPI Fauci Exhibit 36 (11/2/2005 Sykora Dep.), at 25:16 - 25:23, 27:8 - 28:18) Mr. Sykora testified that although he was employed and paid by BIPI, he primarily worked for Roxane. (*Id.*, at 22:20 - 23:5; BIC/BIPI Fauci Exhibit 12 (12/4/2008 Sykora Dep.), at 49:20 - 50:3)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIPI’s separate sales force is material because it goes directly to the corporate separateness of BIPI and Roxane, and, in particular, the separate marketing and sales functions that BIPI and Roxane each had for their drugs. The Government’s additional alleged facts do not controvert BIC and BIPI’s statement of fact and do not create a disputed issue of fact material to their motion for summary judgment. In addition to the reasons stated below, BIC disputes that the additional facts alleged by the Government in its response are material to its motion for summary judgment because they relate solely to BIPI.

BIC and BIPI dispute that BIPI personnel “promoted Roxane’s products, including the Subject Drugs” as this alleged fact is not supported by the Government’s proffered evidence. The Government cites only one example of BIPI’s sales force allegedly promoting a Roxane Subject drug; the situation of ipratropium bromide at the time of its launch. (BIC/BIPI Fauci Ex. 28, 5/17/96 Email to BIPI Sales Force re Atrovent Solution) As described in BIC and BIPI’s Reply to ¶ 7 above, the ipratropium bromide situation was unique because Roxane was launching the generic version of Atrovent, a BIPI brand name drug, and thus, as would be expected, there were certain interactions and cooperation among the companies at the time of launch. (*See* BIC and BIPI’s Reply to SOF ¶ 7) This single example in a unique situation does not establish that BIPI’s sales force regularly promoted Roxane products. Moreover, at the time of Mr. King’s email, May 17, 1996, Roxane’s product had not been launched and BIPI’s sales force was still promoting Atrovent. (BIC/BIPI Fauci Ex. 28, 5/17/96 Email to BIPI Sales Force re Atrovent Solution) Thus, rather than asking BIPI’s

sales force to promote Roxane's product, the e-mail simply asks the sales force to continue promoting the BIPI product, Atrovent, and encourages them to do so by telling them that they will still get credit if their efforts lead to the sale of Roxane's product rather than Atrovent. (*Id.*) Regardless, because this situation does not relate to setting or reporting AWP's for any Subject Drug and reflects at most, a one-time attempt to assist a sister corporation as would be expected by an affiliated company, this alleged fact is immaterial to BIC and BIPI's motion for summary judgment.

BIC and BIPI do not dispute that beginning in October 1998, Mr. King became Head of BIPI/RLI Branded Sales and took on a high-level supervisory role with regard to Roxane's brand and branded generic products in that he supervised two Roxane sales directors and one person responsible for sales training. (BIC/BIPI Fauci Ex. 30, 12/3/04 King Dep. 15; Tab 63, 10/23/98 Reorganization Memo at 3-4) BIC and BIPI dispute that this fact is material to their motion for summary judgment. First, as Professor Macey testified, it is common for affiliated companies to have common management personnel and for employees to wear multiple hats. (BIC/BIPI SOF at ¶ 90) Second, the undisputed testimony of Mr. Berkle is that even though certain BIPI employees, like Mr. King, were added as an additional level of management for Roxane's brand and branded generic products, Roxane employees continued to be responsible for and handled the day-to-day operational sales and marketing activities for these products. (Tab 90, 10/31/08 Berkle Dep. 59-60, 191-92; BIC/BIPI SOF at ¶ 79) Indeed, Roxane's Director of Sales, Jerry Hart, remained the Director of RLI Sales. (Tab 63, 10/23/98 Reorganization Memo at 3; BIC/BIPI Fauci Ex. 50, Berkle Ex. 139 (1999 Roxane Org. Chart)) Moreover, while BIC and BIPI do not dispute that Mr. King was a BIPI employee and paid by BIPI, this is immaterial since, to the extent he was involved in sales and marketing for Roxane's branded generics, he was acting pursuant to the positions and responsibilities he was given at Roxane and on Roxane's behalf. (BIC/BIPI SOF at ¶ 93) Further,

Professor Macey explained that in situations where employees serve dual roles at two companies, the “overwhelming business practice in the United States is to have people receive a single paycheck.” (*Id.*; BIC and BIPI’s Reply to SOF ¶ 93)

BIC and BIPI do not dispute that prior to 2001, Roxane’s National Account Managers in its Trade Relations department had some responsibility for promoting both Roxane and BIPI products to wholesalers and other customers. Nor do BIC or BIPI dispute that Mr. Tupa, a Roxane employee, hired Mr. Feldman, a Roxane employee, as the Director of Trade Relations around 1996 and that Mr. Feldman had some responsibility for promoting both Roxane and BIPI products. BIC and BIPI dispute that these facts are material to their motion for summary judgment. Up until 2001, Mr. Feldman and Roxane’s Trade Relations department primarily focused on Roxane products and only worked with BIPI products on a very limited basis. (Tab 96, 11/4/05 Gordon Dep. 35) As Mr. Sykora explained Roxane’s National Account Managers did not “actively promot[e]” and “weren’t selling” BIPI’s products, but rather at times they “helped on the launch of brand [BIPI] products” in that they would discuss the launch with wholesalers and “provide them information so they could make purchase orders.” (Tab 109, 12/4/08 Sykora Dep. 50-51) Mr. Sykora further explained why it made sense for Roxane’s Trade Relations group to provide this assistance: “Boehringer Ingelheim’s a brand company only. Rather than have a national accounts group that they may only need two or three times a year during a new product launch, it made sense to utilize a subsidiary’s existing national accounts department during those times when they needed it.” (*Id.* at 51-52) Thus, these facts do not relate to setting or reporting AWP for any Subject Drug and do not demonstrate that BIPI was involved in or exerted control over Roxane’s business; rather it demonstrates Roxane and Roxane employees offering assistance to BIPI. Nor do these facts detract

from Roxane's and BIPI's separate corporate identities given each company had separate and distinct products and it would be clear whose products were being promoted.

BIC and BIPI do not dispute that in or around 2001 the Trade Relations employees were split between Roxane and BIPI and Mr. Feldman became a BIPI employee promoting only BIPI products. (BIC/BIPI Fauci Ex. 34, 11/17/04 Feldman Dep. 108-09; Tab 95, 6/25/02 Feldman Dep. 9-10) BIC and BIPI do not dispute that Mr. Sykora, who directed the National Account Managers, reported to Mr. Feldman. BIC and BIPI dispute that Mr. Sykora testified that he was a BIPI employee as this fact is not supported by the Government's proffered evidence. Mr. Sykora testified only that he worked generally for "Boehringer Ingelheim," not that he worked for BIPI. Roxane Laboratories was a subsidiary of Boehringer Ingelheim Corporation and Mr. Sykora later clarified in another deposition that he considered Roxane his employer. (BIC/BIPI Fauci Ex. 12, 12/4/08 Sykora Dep. 50) In addition, the record shows that in fact Mr. Sykora was a Roxane employee until December 2000. (Tab 123, 11/30/00 Letter from Judy Orinski to Robert Sykora at RLI-AWP-00160361-62) BIC and BIPI dispute that these facts are material to their motion for summary judgment.

9. BIPI has its own customers that it contracts with and invoices. (*Id.* 313-14, 322)

United States' Response: The United States does not dispute that BIPI had customers that it contracted with and invoiced. The United States disputes this paragraph to the extent it suggests that Roxane and BIPI did not share customers or market products jointly. Whether BIPI had "its own" customers is immaterial to whether BIPI was involved in the conduct for which the United States is seeking damages.

Further answering, Roxane and BIPI jointly marketed products to customers. For example, in or around August 1996, personnel at Roxane and BIPI discussed the possibility of cooperatively marketing ipratropium bromide to Kaiser, a large group purchasing organization ("GPO"), including by offering better prices if Kaiser committed to purchasing both Roxane and BIPI products. (BIC/BIPI Fauci Exhibit 39) Kaiser ultimately accepted a "bundled agreement" for ipratropium bromide and Atrovent. (BIC/BIPI Fauci Exhibit 40) Judy Waterer explained that "[t]his is another first for us in showing what we can accomplish when we combine the strength of Roxane with BIPI!" (*Id.*)

Another example of joint marketing is Roxane and BIPI's joint bid to Premier (another GPO) in 1998. Premier was at that time Roxane's "#1 customer" and the "largest group purchasing organization." (BIC/BIPI Fauci Exhibit 41) According to a February 27, 1998 Interoffice Memorandum sent to Mr. Berkle, the "primary goal" of the bid to Premier was to maintain the "majority contract item" for BIPI, Roxane and Ben Venue Labs. (BIC/BIPI Fauci Exhibit 42) The memorandum explained that additional discounts on BIPI products "should be held back" until it was certain that Premier "welcomes the BIC companies as a Corporate Partner." (*Id.*)

In addition, Roxane regularly entered into contracts with customers whereby, in return for the customer's marketshare commitment on select Roxane products, the customer received a rebate on its purchase of certain BIPI products. (*See, e.g.,* BIC/BIPI Fauci Exhibit 43, at RLI- AWP-00128923-24)

BIC and BIPI's Reply: The Government does not dispute, and its additional alleged facts do not contradict, the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). BIC and BIPI dispute that Roxane and BIPI "jointly marketed" products to customers, as the phrase is vague, ambiguous and undefined and it is not supported by the Government's proffered evidence. Even if it was supported by the Government's evidence, it is immaterial to BIC and BIPI's motion for summary judgment and the Government's claims against them as the documents the Government references do not demonstrate BIC or BIPI's involvement in setting or reporting AWP's for Roxane's Subject Drugs or marketing the spread on any Subject Drug nor do they demonstrate Roxane lacked independence or that BIPI pervasively controlled Roxane. On the contrary, the documents cited in this paragraph demonstrate only that two distinct companies with separate products were cooperating for the benefit of both companies. This does not equate to "joint marketing" and certainly does not show that BIPI was involved in determining marketing strategy or making marketing decisions for Roxane products.

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 39 indicates that in or around August 1996, personnel at Roxane and BIPI discussed the possibility of offering better prices to

Kaiser if Kaiser committed to purchasing both Roxane ipratropium bromide and BIPI's Atrovent. Nor do BIC and BIPI dispute that BIC/BIPI Fauci Exhibit 40 contains the language quoted by the Government. The Government's quotations, however, are selective, incomplete and misleading; the entirety of the document is the best evidence of its contents. BIC and BIPI dispute that these documents are evidence of "joint" or "cooperative" marketing. Rather, the document merely relates to coordinating a bid for two drugs with regard to one customer and demonstrates only that two distinct companies with separate products were cooperating for the benefit of both companies. The documents do not contradict that each entity has its own customers and for the reasons stated above are immaterial to BIC and BIPI's motion for summary judgment.

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 41 indicates that Premier was at that time Roxane's "#1 customer" and the "largest National GPO." BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 42 contains the language quoted by the Government. The Government's quotations, however, are selective, incomplete and misleading; the entirety of the document is the best evidence of its contents. BIC and BIPI dispute that these documents are evidence of "joint" or "cooperative" marketing. Rather, the documents merely relate to coordinating a bid for specific drugs with regard to one customer and demonstrates only that distinct companies with separate products were cooperating for the benefit of all companies. The documents do not contradict that each entity has its own customers and for the reasons stated above is immaterial to BIC and BIPI's motion for summary judgment.

BIC and BIPI dispute that "Roxane regularly entered into contracts with customers whereby, in return for the customer's marketshare commitment on select Roxane products, the customer received a rebate on its purchase of certain BIPI products" as that is not supported by the Government's proffered evidence. BIC/BIPI Fauci Exhibit 43 at RLI-AWP-00128923-24 is only

evidence of one agreement that Roxane had with one customer, Rite Aid Corporation, which only covered the time period of April 1, 1999 to March 31, 2000. BIC and BIPI do not dispute that under this one agreement, Rite Aid Corporation would receive a rebate on certain BIPI products in return for a marketshare commitment on certain Roxane multisource generic products. BIC and BIPI dispute that this document is evidence of “joint” or “cooperative” marketing. The record shows that in the instances where Roxane offered a rebate on BIPI products in exchange for a certain level of commitment by a customer, it was Roxane, not BIPI, that paid for that rebate. (Tab 101, 2/26/09 McIntyre Dep. 189-90) The document does not contradict that each entity has its own customers and for the reasons stated above is immaterial to BIC and BIPI’s motion for summary judgment.

10. Roxane Laboratories, Inc. (“Roxane”) was first organized in 1885 as Columbus Pharmacal, a small, regional pharmaceutical manufacturer. Columbus Pharmacal was purchased by Philips of the Netherlands, and the name was changed from Columbus Pharmacal to Philips Roxane. (Tab 36, “Roxane Laboratories Oral Solid Dosage Facility Expansion, Columbus, OH”, *available at* <http://www.pharmaceutical-technology.com/projects/roxane/>) It was not until 1978 that Roxane became part of the Boehringer Ingelheim family. (Tab 37, “Boehringer Ingelheim in the United States is available at <http://www.us.boehringer-ingelheim.com/about-us/companyhistory.html>.; Tab 19, 10/11/05 Powers Dep. 198)

United States’ Response: Undisputed.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

11. Roxane was a Delaware corporation during the relevant timeframe, and is headquartered in Columbus, Ohio. (Tab 38, RLI-AWP-00000001-000000069 (1996-2004 Roxane Laboratories, Inc. Corporate Data Sheets) (Roxane Corporate Data))

United States’ Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

12. In April 2005, Roxane Laboratories, Inc. changed its name to Boehringer Ingelheim Roxane, Inc. (“BIRI”). (Roxane’s Answer to United States’ 1st Am. Compl. at 1, n.1; Tab 39, RLI-TX 7922-7923 (Roxane Reorganization Employee Announcement); Tab 40, RLI-AWP- 00104259-62 (9/15/04 Reorg Letter) BIRI remains a Delaware corporation. BIRI continues to manufacture pharmaceutical products. (*Id.*) At the same time, a new entity, Roxane Laboratories, Inc., a Nevada corporation, was incorporated. (*Id.*) As of that time, the new Nevada corporation (“RLI Nevada”) assumed responsibilities for sales and marketing of pharmaceutical products sold under the Roxane tradename. (*Id.*)

United States’ Response: Undisputed. Further answering, the April 2005 reorganization was undertaken, at least in part, due to a recognition that Boehringer Ingelheim “operate[d] in the U.S. with a variety of legal entities that do not necessarily reflect the nature of [its] businesses,” resulting “in two sets of reporting: one in terms of legal entities and another in terms of businesses.” (BIC/BIPI Fauci Exhibit 44, at BICJURIS 1066). Prior to 2005, Roxane had separate reporting structures for its manufacturing business and for its sales and marketing business. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 29:14 - 30:12) There was a concern at Boehringer Ingelheim that “[t]his system often [did] not convey clearly the performance of our businesses, and le[d] to complexities in interpreting how each business is faring.” (BIC/BIPI Fauci Exhibit 44) An October 13, 2004, Employee Bulletin announcing the April 2005 reorganization explained that due to organizational changes made in or around 2000, “the employee and financial reporting structures were crossing the businesses” at Roxane, BIPI and Ben Venue Labs, requiring Boehringer Ingelheim to spend a significant amount of time trying to accurately report on the performance of each business. (BIC/BIPI Fauci Exhibit 46) The Bulletin also explained that the 2005 Reorganization would help to “better align employees with the businesses they support and the management group they report to” and to place “employees within the same legal entity they report to.” (*Id.*) Hermann Tetzner (BIC Chief Financial Officer) also testified that the reorganization was also intended to reduce potential legal liability. (BIC/BIPI Fauci Exhibit 6 (Tetzner Dep.), at 30:1 - 33:5)

Multiple Roxane employees testified that prior to 2005, Roxane and BIPI operated as intermingled companies. (*See, e.g.,* BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.), at 13:12 - 14:1 (noting that Boehringer Ingelheim was “kind of an intermingled company”); BIC/BIPI Fauci Exhibit 47 (2/4/2003 Powers Dep.), at 40:23 - 42:1; BIC/BIPI Fauci Exhibit 48 (email from BIPI employee regarding Roxane and BIPI’s pricing process and asking “Now that we are one Corporation, should these processes be combined . . .”)) Moreover, Boehringer Ingelheim employees observed that Roxane and BIPI appeared to be one company to customers. For example, in April 1997, Jim King drafted a memorandum regarding Roxane’s pricing procedures. (BIC/BIPI

Fauci Exhibit 49) In a section entitled “Recommendations,” Mr. King noted that Roxane and BIPI “do not appear too separate to people outside our Corporation,” and advised that it was important to convene a pricing committee regularly “to ensure that pricing issues are squared away at both companies.” (*Id.*, at BOEH04353265)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Disputed that the facts alleged in the Government’s response are material to BIC and BIPI’s motion for summary judgment. Although immaterial, BIC and BIPI do not dispute that the documents and depositions cited by the Government contain the facts and quotations referenced therein. The Government’s characterizations and quotations, however, are selective and incomplete; the documents and depositions in their entirety are the best evidence of their content.

As the Government itself points out, the main reason for the April 2005 reorganization was to resolve issues relating to the fact that while Roxane was a single legal entity, it “had separate reporting structures for its manufacturing business and for its sales and marketing business.” (BIC/BIPI Fauci Ex. 44, Boehringer Ingelheim Legal Entity Project Presentation at BICJURIS 1066) As James McIntyre explained, the April 2005 restructuring sought to divide the two businesses within Roxane, operations and sales, into separate legal entities:

Roxane Laboratories is a legal entity. But the sales is sales and marketing, and . . . the operations piece is a manufacturing. We report separately in terms of . . . the performance results for those two segments of that particular company, so we really had two businesses within that one legal entity. And that’s what the . . . reorganization was trying to fix.

(Tab 101, 2/26/09 McIntyre Dep. 30) Although immaterial to this fact, BIC and BIPI do not dispute that the October 13, 2004 Employee Bulletin included the statements in the Government's citations. BIC and BIPI do dispute, however, any implication that the performance of Roxane, BIPI and Ben Venue Laboratories, Inc. was inaccurately reported. Rather, the Employee Bulletin indicates that "the Company" spent "a significant amount of time" to ensure that each business's performance was accurately reported. (BIC/BIPI Fauci Ex. 46, 10/13/04 Employee Bulletin re Future Strategies at RLI-AWP-00107262) The creation of "two separate entities" was intended to "simplify" the "budgeting and reporting schemes." (*Id.* at RLI-AWP-00107263) Finally, the Employee Bulletin notes that some of the "business benefits" of the reorganization were the "[c]omplete focus of BI Roxane Inc. on Manufacturing, supporting the strategic decision to establish Roxane as an international manufacturing site for Sprivia® and other BI products" and "[s]implification of allocation and reporting schemes by having a clear distinction between the Manufacturing business and the multisource Development, Sales, and Marketing business." (*Id.*) Thus, rather than reorganizing Roxane's sales and marketing department under another company, the department became a separate, independent company. BIC and BIPI note that the time and effort devoted to re-organizing Roxane confirms the Boehringer Ingelheim companies' commitment to maintaining separate, well-structured, independently-run companies.

BIC and BIPI also dispute the 2005 reorganization was intended to avoid legal liability. Although it is undisputed that Hermann Tetzner testified that one of the reasons for the reorganization was "to reduce potential legal liability," the Government's characterization of his testimony is selective and incomplete; the deposition in its entirety is the best evidence of its content. Mr. Tetzner testified that the "liability issue was not the major driver of this project," and that the point was to allocate responsibility between the marketing and sales of products and the

manufacturing of products: “we want it to separate liabilities from either a manufacturing process or a marketing and sales process.” (BIC/BIPI Fauci Ex. 6, 10/19/04 Tetzner Dep. 30-31) Tetzner further explained that the point was to allocate and separate liabilities between manufacturing and sales and marketing and make “people accountable for their function for their business.” (*Id.* at 31) Mr. McIntyre underscored this point, noting that liability considerations made in connection with the 2005 reorganization were focused on “trying to align liability with the business, so if manufacturing had a – if there was a manufacturing liability, the manufacturing legal entity was – was accountable for that. So we’re just trying to align liability with the business.” (Tab 101, 2/26/09 McIntyre Dep. 176-77)

Although it is undisputed that Ms. Waterer testified as the Government quotes, the testimony cited by the Government is immaterial, selective, and incomplete; the deposition testimony in its entirety is the best evidence of its content. Specifically, Ms. Waterer’s quote was made in response to a line of questions about attorney Bruce Banks, and she was hesitating to answer about his position because she believed it raised various legal definitions and distinctions to which she could not speak. (BIC/BIPI Fauci Ex. 11, 10/24/01 Waterer Dep. 13-15 (“I’m not sure. We’re [BIC] kind of an intermingled company. . . . [T]here are a lot of legal definitions for what I consider to be different branches of the company. . . . I’m not the one that can answer his position. . . . I don’t know how that works. . . . And I’m not going to do well with answering it because it’s a lot of legal definitions for how things are incorporated.”))

Undisputed that Mr. Powers testified as stated by the Government, but the testimony is immaterial, selective, and incomplete; the deposition testimony in its entirety is the best evidence of its content. Mr. Powers was speaking in the context of the contracts department, not the company as a whole. (BIC/BIPI Fauci Ex. 47, 2/4/03 Powers Dep. 40-42) And indeed, the Roxane contracts

administration department was eventually combined with the BIPI contracts department into a single unit that provided centralized contract administration services to both Roxane and BIPI; Roxane was charged back for these services. (BIC/BIPI SOF at ¶ 49) BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 48 includes the quoted statement, but dispute the portions cited by the Government as immaterial, selective, and incomplete; the email in its entirety is the best evidence of its content. Specifically, it is not clear what “one Corporation” means, nor has the Government cited testimony or evidence indicating what the author meant. Additionally, the Government has cited no testimony or evidence that BIPI and Roxane actually had a combined pricing process before this email was sent, nor is there an indication from this document that any combined pricing process occurred after the email was written.

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 49 includes the quoted statements, but dispute the portions cited by the Government as immaterial. Specifically, Mr. King’s draft, non-final, internal memorandum does not provide a basis for his statement that Roxane and BIPI “do not appear too separate to people outside our corporation,” nor is there testimony to provide that basis. (BIC/BIPI Fauci Ex. 49, 4/7/97 Email re Draft Pricing Memo at BOEH04353265) On the contrary, the testimony demonstrates that Roxane and BIPI were entirely separate companies. (Tab 101, 2/26/09 McIntyre Dep. 117 (“[Q]: Roxane and BIPI are separate companies, correct? A: Correct.”); Tab 90, 10/31/08 Berkle Dep. 38 (“Roxane was a separate business entity. They had their own budgets, their own plans. . . . Roxane had its own management team and it was responsible for the annual budgets, marketing plans, day-to-day operations.”); Tab 109, 12/4/08 Sykora Dep. 48-49 (“Roxane operated as an independent unit within the Boehringer Ingelheim family of companies, so any decisions that we made, they were Roxane decisions, they weren’t Boehringer decisions There was a kind of an indirect reporting relationship between Roxane and Boehringer, but [Roxane]

ran as a completely standalone company.”)) Furthermore, Roxane had its own customers, entered into its own contracts, had its own labels and labeler code, and marketed and sold its own products.

(*See, e.g.*, BIC/BIPI SOF at ¶¶ 10-18)

13. At all times relevant to this litigation, Roxane was a wholly-owned subsidiary of BIC. (Tab 29, 5/11/07 Waterer Dep. 523)

United States’ Response: Undisputed.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

14. Roxane had its own employees, whom it retained the ability to hire and fire and to whom it offered its benefits plans that were different than those of its affiliates. (Tab 41, RLI-TX 17676-78 (Roxane Reorganization Human Resources Presentation))

United States’ Response: The United States does not dispute that Roxane had employees over whom it retained the ability to hire and fire. However, the United States disputes that all or even most personnel who marketed and/or sold Roxane’s products were Roxane employees. As noted *supra* in the United States’ responses to Paragraphs 7 and 8, various BIPI personnel were involved in the marketing and/or promotion of Roxane’s products, including the Subject Drugs. In fact, the two senior managers in charge of Roxane’s marketing in the 1998 - 2001 time frame were Mr. Berkle and Tom Russillo, neither of whom was employed by Roxane. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 205:19 - 207:2) Mr. Berkle was employed by BIPI, but supervised Roxane’s branded generic business. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18, 59:17 - 60:11, 262:19 - 264:12, 337:8 - 339:16, 341:17 - 342:4) Mr. Russillo was employed as the Chief Operating Officer of Ben Venue Laboratories, but was in charge of marketing for Roxane’s “multi-source products.” (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 22:17 - 25:3, 29:8 - 30:10)

In addition, a Roxane organizational chart from 1999 (BIC/BIPI Fauci Exhibit 50) identifies several BIPI employees as having responsibility for Roxane’s drugs, including, among others, James King, Gregg Ciarelli, and Mike Leonetti.

- Mr. King testified that although he had supervised Roxane sales personnel, he was employed by BIPI for his entire career and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 11:13 - 12:4, 15:2 - 15:23, 25:15 - 26:8)

- Mr. Ciarelli testified that although he was employed and paid by BIPI for his entire tenure with Boehringer Ingelheim, (BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.), at 9:17 - 10:11, 50:6 - 50:13), his job responsibilities as marketing controller encompassed the entire “Business Unit” including BIPI and Roxane.

(*Id.*, at 13:14 - 14:7) Mr. Ciarelli testified that he likely appeared on a Roxane organizational chart because he “had people on the Roxane payroll that reported to [him].” (*Id.* at 50:14 - 50:18)

Mr. Ciarelli also testified that from 1997 through 2000, he had “ongoing responsibility” for reporting prices to First Data Bank for Roxane’s branded products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.), at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21) In addition, Mr. Berkle testified that Mr. Ciarelli was responsible for ensuring that Roxane and BIPI complied with applicable laws regarding the reporting of drug prices. (BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 166:23 - 168:11)

- Mr. Leonetti worked for BIPI (BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 219:19 - 220:7; BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.), at 125:15 - 126:6), but supervised the Trade Relations Group and the “Reimbursement Manager,” each of which had responsibilities for Roxane products. (BIC/BIPI Fauci Exhibit 36 (11/2/2005 Sykora Dep.), at 26:8 - 28:11; BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.), at 181:17 - 183:7)

Effective January 2002, senior employees responsible for marketing Roxane’s multi-source products, including Judy Waterer and Leslie Paoletti, were transferred to Ben Venue Laboratories. (BIC/BIPI Fauci Exhibit 55) From this time forward, Ms. Waterer and Ms. Paoletti continued to have responsibility for marketing Roxane’s products even though they were employed and paid by Ben Venue Labs. (BIC/BIPI Fauci Exhibit 56 (11/9/2004 Paoletti Dep.), at 9:25 - 10:23, 17:1 - 17:6; BIC/BIPI Fauci Exhibit 57 (7/26/2007 Paoletti Dep.), at 9:16 - 10:9; BIC/BIPI Fauci Exhibit 58 (11/28/2005 Waterer Dep.), at 28:14 - 29:2)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). The Government’s additional facts do not contradict this statement of fact and are immaterial to BIC and BIPI’s motion for summary judgment.

BIC and BIPI dispute the Government’s statement disputing that “all or even most personnel who marketed and/or sold Roxane’s products were Roxane employees” as it is not supported by

proper citations to the record. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding “purported statements of ‘fact’ not properly supported by citations to the record” in summary judgment pleadings as required by Local Rule 56.1). Roxane employees were responsible for and handled the day-to-day operational sales and marketing activities for Roxane’s products. (Tab 90, 10/31/08 Berkle Dep. 38, 50-51, 59-60, 191-92; BIC/BIPI SOF at ¶¶ 52-54, 79) Further, Roxane’s Sales and Marketing Department was also responsible for setting and changing the AWP’s for Roxane’s products. (BIC/BIPI SOF at ¶¶ 54, 63) BIC and BIPI dispute that “BIPI personnel were involved in the marketing and/or promotion of Roxane’s products, including the Subject Drugs.” (*See* BIC and BIPI’s Reply to SOF ¶¶ 7-8)

BIC and BIPI do not dispute that Mr. Berkle was not employed by Roxane, but do dispute that Mr. Berkle was “in charge of Roxane’s marketing in the 1998-2001 time frame.” The undisputed testimony of Mr. Berkle is that he only had high-level, strategic oversight over Roxane’s sales and marketing business and was not involved in its day-to-day operations. (Tab 90, 10/31/08 Berkle Dep. 38 (Berkle only had “strategic oversight of Roxane, [] Roxane had its own management team and it was responsible for the annual budgets, marketing plans, day-to-day operations.”), 51 (“I really had a strategic involvement with Roxane, not an operational day-to-day involvement.”), 76, 125, 186-87; Tab 89, 1/27/05 Berkle Dep. 23-24; BIC/BIPI SOF at ¶¶ 78-79) Mr. Tupa, a Roxane employee, continued to lead Roxane’s Marketing and Sales department and handle the day-to-day operational marketing and sales activities. (Tab 61, 5/3/96 Reorganization Announcement (“The Roxane Marketing & Sales Department will be led by Mr. Edward Tupa, who currently has this responsibility.”); Tab 90, 10/31/08 Berkle Dep. 50-51) Thus the Government’s fact is immaterial because it does not demonstrate that Mr. Berkle had any involvement in setting or reporting AWP’s for any Subject Drug not does it show that he pervasively controlled Roxane. This fact is also

immaterial, as any involvement Mr. Berkle did have in any material sales and marketing decisions for Roxane products was done on behalf of Roxane pursuant to his roles as director of Roxane and Head of the Business Unit. There is no basis to impute his actions to BIPI. (*See* BIC and BIPI's Reply to SOF ¶ 7) Further, BIC and BIPI do not dispute that when Mr. Russillo became the head of Roxane's multisource products in 1998, Mr. Russillo also was the President and COO of a separate BIC subsidiary, Ben Venue Laboratories, Inc.. (*See* BIC and BIPI's Reply to SOF ¶ 57) However, this is immaterial as any decisions by Mr. Russillo relating to Roxane's multisource products during this timeframe would have been made in Mr. Russillo's Roxane role, not Mr. Russillo's Ben Venue role. As Professor Macey testified, it is common for affiliated companies to have common management personnel and for employees to wear multiple hats. (BIC/BIPI SOF at ¶ 90)

BIC and BIPI do not dispute that beginning in October 1998, Mr. King became Head of BIPI/RLI Branded Sales and took on a high-level supervisory role with regard with Roxane's brand and branded generic products in that he supervised two Roxane sales directors and one person responsible for sales training. (Tab 97, 12/3/04 King Dep. 15; Tab 63, 10/23/98 Reorganization Memo at 3-4) BIC and BIPI dispute that this fact is material to their motion for summary judgment. First, as Professor Macey testified, it is common for affiliated companies to have common management personnel and for employees to wear multiple hats. (BIC/BIPI SOF at ¶ 90) Second, the undisputed testimony of Mr. Berkle is that even though certain BIPI employees, like Mr. King, were added as an additional level of management for Roxane's brand and branded generic products, Roxane employees continued to be responsible for and handled the day-to-day operational sales and marketing activities for these products. (Tab 90, 10/31/08 Berkle Dep. 59-60, 191-92; BIC/BIPI SOF at ¶ 79) Indeed, Roxane's Director of Sales, Jerry Hart, remained the Director of RLI Sales. (Tab 63, 10/23/98 Reorganization Memo at 3-4; BIC/BIPI Fauci Ex. 50, 1/27/05 Berkle Ex. 139,

1999 Roxane Org. Chart) Moreover, while BIC and BIPI do not dispute that Mr. King was a BIPI employee and paid by BIPI, this is immaterial since, to the extent he was involved in sales and marketing for Roxane's branded generics, he was acting pursuant to the positions and responsibilities he was given on behalf of Roxane. (BIC/BIPI SOF at ¶ 93) Further, Professor Macey testified that in situations where employees serve dual roles at two companies, the "overwhelming business practice in the United States is to have people receive a single paycheck." (BIC/BIPI SOF and Reply to SOF ¶ 93) BIC and BIPI also incorporate their Reply to ¶ 51.

BIC and BIPI dispute that Mr. Ciarelli had responsibilities for the entire Roxane business. In an effort to leverage the expertise and experiences of several BIPI employees for the benefit of Roxane, Mr. Ciarelli and Mr. Leonetti were given additional high-level supervisory positions for Roxane's brand and branded generic products — not all of Roxane's products — in October 1998. (Tab 90, 10/31/08 Berkle Dep. 191-92); *see also* BIC and BIPI's Reply to SOF ¶ 51) However, BIC and BIPI dispute that "from 1997 through 2000, [Mr. Ciarelli] had 'ongoing responsibility' for reporting prices to First Data Bank for Roxane's branded products" as this fact is not supported by the Government's proffered evidence, BIC/BIPI Fauci Exhibit 52. In his testimony, Mr. Ciarelli does not testify that BIPI personnel reported AWP's to the pricing compendia for Roxane's branded and branded generic products. Rather, Mr. Ciarelli testifies that "one of the people in Roxane who reported to me, John Powers, reported those prices." (BIC/BIPI Fauci Ex. 52, 7/25/07 Ciarelli Dep. 24) Thus, this fact is immaterial to BIC and BIPI's motion for summary judgment. Moreover, to the extent that Mr. Ciarelli may have had any material involvement in reporting prices for Roxane's brand and branded generic products, it is immaterial to BIC and BIPI's motion for summary judgment and the Government's direct liability claims against them as Mr. Ciarelli was acting on behalf of Roxane pursuant to the role and responsibilities he had been given for Roxane's brand and

branded generic products, and therefore his conduct cannot be imputed to BIPI. (Tab 92, 7/25/07 Ciarelli Dep. 21-23; Tab 63 at 4, 10/23/98 Reorganization Memo at 4; BIC/BIPI SOF at ¶ 93; *see also* BIC and BIPI's Reply to SOF ¶ 51) Moreover, Mr. Ciarelli's role with regard to Roxane's branded generic products is immaterial to BIC and BIPI's motion for summary judgment and the Government's veil-piercing claims against them because it is common for affiliated companies to have overlapping managers and the evidence does not suggest that Mr. Ciarelli exercised pervasive control over any part of Roxane's business. In addition, BIC disputes that this additional fact is relevant to its motion for summary judgment or the Government's claims against it because it relates solely to BIPI.

BIC and BIPI do not dispute that in 2002 Ms. Waterer and Ms. Paoletti began to be paid by Ben Venue because Ms. Waterer and Ms. Paoletti physically moved from Roxane's campus in Columbus, Ohio, to Ben Venue's campus in Bedford, Ohio. (Tab 98, 5/19/09 Macey Dep. 253-54) However, because Ms. Waterer and Ms. Paoletti only had Roxane responsibilities and were "fully allocated" to Roxane, Roxane was charged back by Ben Venue for the salaries paid to Ms. Waterer and Ms. Paoletti. (Tab 101, 2/26/09 McIntyre Dep. 63-65; Tab 102, 11/9/04 Paoletti Dep. 11) Indeed, there was a sign outside Ms. Paoletti's and Ms. Waterer's offices at the Bedford campus that said "Roxane Laboratories." (Tab 102, 11/9/04 Paoletti Dep. 10-11) Professor Macey testified that it is common for employees to receive the paycheck from the business entity where they are physically located. (Tab 98, 5/19/09 Macey Dep. 253-55) BIC and BIPI also dispute that these facts are material to the Government's veil-piercing claims as they relate to actions by Ben Venue, not BIPI or BIC.

15. Roxane has its own separate line of Roxane-labeled products that it marketed under its own name and labeler code. Currently, the Roxane product line consists of roughly 400-500 NDCs. (Tab 6, 5/30/07 DeCapua Dep. 167; Tab 13, 6/27/02 Marsh Dep. 117; Tab 2, 10/31/08 Berkle Dep. 320-21)

United States' Response: Undisputed, except that BIPI at times was identified in the launch of Roxane products, including Roxicodone. For example, product announcements for Roxane's 15 mg and 30 mg Roxicodone tablets identified the product as "From Boehringer Ingelheim/Roxane Laboratories, Inc." (BIC/BIPI Fauci Exhibit 59) Likewise, a promotion for Roxane's Cafcit product (not a Subject Drug) stated that "Roxane Laboratories, Inc., in conjunction with Boehringer Ingelheim Pharmaceuticals, Inc. is pleased to announce the availability of Cafcit." (BIC/BIPI Fauci Exhibit 106)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 59 contains the quoted language, but dispute that BIPI was identified in the launch of Roxicodone. The quoted language merely says "Boehringer Ingelheim," indicating that Roxane is part of the Boehringer Ingelheim family of companies. Nowhere is Boehringer Ingelheim Pharmaceuticals, Inc. identified. In addition, BIC and BIPI dispute that this fact is material to their motion for summary judgment or the Government's direct liability and veil-piercing claim against them because does not relate to setting, approving or reporting AWP's, nor does it demonstrate pervasive control or fraudulent purpose by BIPI as is necessary to justify piercing the corporate veil.

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 106 contains the quoted language, but dispute that this fact is material to the Government's claims against them as it relates to Cafcit, a drug that is not one of the Subject Drugs at issue in this case.

In addition, BIC disputes that either document is material to its motion for summary judgment or the Government's direct liability or veil-piercing claims against it because the Government only alleges that this fact relates to BIPI.

16. Roxane has always been primarily focused on marketing multi-source products. Until 2001, Roxane also marketed a small line of brand and branded generic products. (Tab 2, 10/31/08 Berkle Dep. 30-31; Tab 14, 5/31/07 Marsh Dep. 28-29; Tab 6, 5/30/07 DeCapua Dep. 15-16; *infra* ¶ 81)

United States' Response: Disputed. According to a Roxane "Position Paper" from 1999, Roxane's "largest seller" at that time was Viramune®, an HIV/AIDS drug assigned to Roxane by BIPI, which accounted for \$106 million of Roxane's expected \$412 million in third-party net sales for 1999. (BIC/BIPI Fauci Exhibit 60, at BOEH02601796) The Position Paper described Roxane's "branded generics" in the pain/palliative care area as "important contributors to its sales and profits." (*Id.*) The Position Paper specifically noted that Oramorph SR, Roxicodone and Roxanol (all branded generic products and all Subject Drugs) collectively produced sales of \$40 million in 1999. (*Id.*)

BIC and BIPI's Reply: The Government's response does not create an issue of disputed fact material to BIC and BIPI's motion for summary judgment. The Government does not dispute that the cited deposition testimony supports that Roxane has always been primarily focused on marketing multi-source products or that until 2001, Roxane also marketed a line of branded and branded generic products; those facts are therefore deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

The Government's dispute that Viramune was Roxane's "largest seller" in 1999 is immaterial, and does not contradict the substance of the statement of fact that Roxane's brand and branded generic line was small relative to its multisource line. Even if Viramune, Roxicodone, Oramorph SR and Roxanol accounted for \$146 million of Roxane's \$412 million of sales, the vast majority of sales dollars are still attributable to Roxane's multisource line. (BIC/BIPI Fauci Ex. 60, 12/6/99 Email re Position Paper at BOEH02601796) Additionally, Viramune, Oramorph SR, Roxicodone, and Roxanol are only a few products out of the roughly 400-500 NDCs that have historically been in the Roxane product line. (Tab 93, 5/30/07 DeCapua Dep. 167) Thus, Roxane's line of brand and branded generic drugs was small relative to the number of its multisource products.

In addition, BIC and BIPI dispute that the Government's additional fact is material to the Government's claims against them as it relates to a drug, Viramune, that is not one of the Subject Drugs at issue in this case.

17. Roxane promotes its products primarily based on price and service to wholesalers and pharmacies. (Tab 29, 5/9/07 Waterer Dep. 102-103; Tab 29, 5/11/07 Waterer Dep. 538-540) Roxane had its own customers with whom it negotiated and entered into contracts. (Tab 29, 5/11/07 Waterer Dep. 547-51, 558-59)

United States' Response: The United States disputes that Roxane "promotes its product primarily based on price and service to wholesalers and pharmacies." The United States refers to its Local Rule 56.1 Statement of Undisputed Material Facts As to The Roxane Defendants (M.D.# 6293, S.D.# 299), which demonstrates that Roxane knowingly set inflated AWP's for its products and promoted increased reimbursement as a reason for customers to purchase its products.

The United States does not dispute that Roxane had customers that it contracted with and invoiced. The United States disputes this paragraph to the extent it suggests that Roxane and BIPI did not share customers or market products jointly. Whether Roxane had "its own" customers is immaterial to whether Roxane was involved in the conduct for which the United States is seeking damages. Further answering, *see supra* United States' Response to Paragraph 9.

BIC and BIPI's Reply: The Government's response does not create an issue of disputed fact material to BIC and BIPI's motion for summary judgment. The Government does not dispute that Roxane had its own customers with whom it negotiated and entered into contracts and therefore these facts are deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). This fact is material because it supports that Roxane operated as a separate, independent company from BIC and BIPI. BIC and BIPI incorporate their Reply to ¶ 9.

While the Government disputes the first sentence of BIC and BIPI's statement of fact, BIC and BIPI object to the Government's dispute on the grounds that the Government failed to provide specific references and instead cites to its entire Local Rule 56.1 Statement of Undisputed Material Facts As to The Roxane Defendants. Because the Government has failed to provide specific record

citations in support of its dispute, the first sentence of BIC and BIPI's statement of fact should be deemed admitted as well.

BIC and BIPI dispute that Roxane knowingly set inflated AWP's for its products and promoted increased reimbursement as a reason for customers to purchase its products and incorporate Roxane's Response to the United States' Local Rule 56.1 Statement of Undisputed Material Facts as to the Roxane Defendants. More specifically, BIC and BIPI dispute that "Roxane knowingly set inflated AWP's for its products" as Roxane did not believe AWP's to be actual averages of acquisition costs and believed the Government had the same understanding. (*See* Roxane's Reply to SOF at ¶¶ 99-102) BIC and BIPI also dispute that Roxane "promoted increased reimbursement as a reason for customers to purchase its products." Rather, Roxane's corporate representative testified that Roxane competed on contract price, and it was not Roxane's general practice to concern itself with the spread except in the "exceptional case" where it was brought to its attention that Roxane's AWP's were out of line with the norm. (Tab 111, 5/9/07 Waterer Dep. 103-04) BIC and BIPI further incorporate Roxane's Responses to ¶¶ 105-110 of the US' SOF re Roxane.

18. Roxane has its own FDA labeler code, which is 00054. (Tab 18, 7/26/07 Paoletti Dep. 200)

United States' Response: Undisputed. *See supra* United States' Response to Paragraph 15.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). BIC and BIPI incorporate their Reply to ¶ 15.

19. Sales and marketing practices for brand and generic products are very different based on the nature of each market. (Tab 2, 10/31/08 Berkle Dep. 321; Tab 29, 5/9/07 Waterer Dep. 199-200; Tab 26, 10/24/01 Waterer Dep. 142-143)

United States' Response: The phrase “very different” is ambiguous as used in this paragraph. The United States does not dispute that branded and multi-source products may be marketed according to different marketing strategies. The paragraph is otherwise disputed, and is not supported by the cited authority.

BIC and BIPI's Reply: The Government does not dispute that brand and generic products may be marketed using various marketing strategies. While the Government “otherwise” disputes the statement of fact, the Government provides no explanation as to how BIC and BIPI's citations are deficient. BIC and BIPI's statement of fact is supported by its citations. Accordingly, BIC and BIPI's entire statement of fact should be deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

20. Brand drugs are marketed mainly to physicians, based upon their clinical benefits. (Tab 26, 10/24/01 Waterer Dep. 142; Tab 29, 5/9/07 Waterer Dep. 199-200) This is because brand drugs are patent protected, so as long as a prescription is written for that drug, it will be dispensed. (Tab 26, 10/24/01 Waterer Dep. 142-143) Multi-source generic drugs are marketed mainly to wholesalers and retail pharmacies based on service and price. (Tab 2, 10/31/08 Berkle Dep. 322; Tab 29, 5/9/07 Waterer Dep. 199-200, *supra* ¶ 17)

United States' Response: Disputed. Roxane has failed to offer evidence to support a finding that brand drugs “are marketed mainly to physicians, based upon their clinical benefits” or that “multi-source generic drugs are marketed mainly to wholesalers and retail pharmacies based on service and price.” The United States refers to its Local Rule 56.1 Statement of Undisputed Material Facts As to The Roxane Defendants (M.D.# 6293, S.D.# 299), which demonstrates that Roxane knowingly set inflated AWP's for its products and promoted increased reimbursement as a reason for customers to purchase its products. Further answering, Roxane marketed several multi-source products as “branded generic” products, meaning that the product was assigned a brand name and was marketed according to a branded marketing strategy. (*See, e.g.*, BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 31:8 - 31:22; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 30:14 - 33:6)

BIC and BIPI's Reply: The Government's response does not create a disputed issue of fact material to BIC and BIPI's motion for summary judgment. While the Government disputes the

statement of fact, the Government provides no explanation as to how BIC and BIPI's citations are deficient. This statement of fact is properly supported by the cited testimony of Ms. Waterer and Mr. Berkle and thus should be deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

BIC and BIPI object to the Government's dispute on the grounds that the Government failed to provide specific references and instead cites to its entire Local Rule 56.1 Statement of Undisputed Material Facts as to The Roxane Defendants. BIC and BIPI dispute that the United States' Statement of Undisputed Material Facts As To The Roxane Defendants demonstrates that Roxane "knowingly set inflated AWP's for its products and promoted increased reimbursement as a reason for customers to purchase its products." BIC and BIPI incorporate Roxane's Responses to the US' SOF re Roxane.

More specifically, BIC and BIPI dispute that "Roxane knowingly set inflated AWP's for its products" as Roxane did not believe AWP's to be actual averages of acquisition costs and believed the Government had the same understanding. (*See* Roxane Reply to SOF at ¶¶ 99-102) BIC and BIPI also dispute that Roxane "promoted increased reimbursement as a reason for customers to purchase its products" Rather, Roxane's corporate representative testified that Roxane competed on contract price, and it was not Roxane's general practice to concern itself with the spread except in the "exceptional case" where it was brought to its attention that Roxane's AWP's were out of line with the norm. (Tab 111, 5/9/07 Waterer Dep. 103-04) BIC and BIPI further incorporate Roxane's Responses to ¶¶ 105-110 of the US' SOF re Roxane.

BIC and BIPI dispute that “Roxane marketed several multi-source products as ‘branded generics’” because the term is vague, ambiguous and undefined, the Government does not specify which Subject Drugs it believes were marketed as “branded generics” and for the reasons set forth in Roxane’s Response to ¶ 7 of the United States’ Statement of Facts as to Roxane. BIC and BIPI incorporate Roxane’s Responses to ¶ 7 of the US’ SOF re Roxane.

II. Roxane Respected All Corporate Formalities And Maintained Independent Financial Records And Sufficient Capitalization.

(a) Roxane Had a Fully-Functioning Board of Directors

21. Roxane had its own Board of Directors. From 1996 until 2005, Roxane’s Board ranged in size from three to five directors, and included the following individuals: Werner Gerstenberg, Gerald Wojta, Phillip Franks, Walter Poerschman, Sheldon Berkle, Martin Carroll, and Robert Fromuth. (Tab 38, RLI-AWP-00000001-00000069 (Roxane Laboratories, Inc. Corporate Data Sheets) (Roxane Corporate Data))

United States’ Response: The United States does not dispute that Roxane had a Board of Directors. The United States disputes that this board was “fully-functioning.” Mr. Berkle, the only member of the Roxane Board of Directors who has been deposed, testified that the Roxane Board of Directors “was not an active board” and that “there were very, very infrequent meetings and it was more to form than anything else. It wasn’t operational in other words.” (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 54:9 - 54:19) Further answering, the Roxane Board of Directors met rarely if ever. (*Id.*)

BIC and BIPI’s Reply: The Government does not dispute that Roxane had its own Board of Directors and that from 1996 until 2005, Roxane’s Board ranged in size from three to five directors, and included the following individuals: Werner Gerstenberg, Gerald Wojta, Phillip Franks, Walter Poerschman, Sheldon Berkle, Martin Carroll, and Robert Fromuth; those facts are therefore deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

BIC and BIPI do not dispute that Mr. Berkle’s deposition testimony contains the quoted language. The Government’s quotations, however, are selective and incomplete; the entirety of the

deposition is the best evidence of its contents. Mr. Berkle repeatedly stated that he was unable to recall details about Roxane's Board. (Tab 90, 10/31/08 Berkle Dep. 53-54) Further, Mr. Berkle's testimony that the Roxane Board did not meet does not mean it was not fully-functioning. As described in ¶¶ 21-29, Roxane's Board conducted all of the functions expected by a Board and acted through unanimous written consents, which is explicitly permitted by Roxane's bylaws and Delaware law. (*See* 8 Del. Gen. Code § 141(f); Tab 42, Roxane Unanimous Consents, Bylaws of Roxane Laboratories, Inc. at BOEH04600117-614, BOEH04600229-247) As the Roxane Board appropriately functioned through unanimous written consents in accordance with its bylaws and Delaware law, Mr. Berkle's statements regarding his faded recollection are immaterial to BIC and BIPI's motion for summary judgment.

22. In accordance with its bylaws and Delaware law, Roxane's Board acted through unanimous written consent, in lieu of meetings, to choose officers, directors, a chairman of the board, and to transact other company business. Roxane maintained written records of the Board's bylaws and unanimous consents. (Tab 42, BOEH04600117-21, BOEH04600151-54, BOEH04600159-67, BOEH04600197-09, BOEH04600226-47, BOEH04600248-52; BOEH04600254-63, BOEH04600267, BOEH04600292-94, BOEH04600302-06, BOEH04600326-28, BOEH04600330-39, BOEH04600363-77, BOEH04600382-85, BOEH04600392-97, BOEH04600413-15, BOEH04600430-35, BOEH04600465-77, BOEH04600504-07, BOEH04600521-29, BOEH04600533-36, BOEH04600538-44, BOEH04600609-14 (Select Roxane Board of Directors Unanimous Written Consents 1996- 2005) (Roxane Unanimous Consents))

United States' Response: The United States does not dispute that Roxane's Board of Directors at times chose officers and directors and took other actions through "unanimous written consent." The United States disputes that this is material to whether or not Roxane operated as an independent company, however. First, Mr. Berkle testified that the Roxane Board was not "active" and "was more to form than anything else." (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 54:9 - 54:19) Second, Roxane expert witness, Professor Macey, testified that at a corporation of Roxane's size, "corporate formalities" such as "board processes" and "board action" are almost always followed. (BIC/BIPI Fauci Exhibit 61 (5/20/2009 Macey Dep.), at 292:11 - 294:22) Third, Roxane has not offered any evidence to establish who created the unanimous written consents, nor whether or not they were prepared by counsel. Finally, when the Roxane Board of Directors acted through unanimous written consents, it was at times merely to confirm or formally authorize decisions that had already been made by BIC and/or BIPI. (*See infra* United States' Response to Paragraph 27)

Further answering, on several occasions, the Roxane Board of Directors simply authorized employees of Roxane's affiliate companies, including BIPI, to perform various functions with regard

to Roxane's business. For example, in or around February 18, 1999, Roxane's Board of Directors acted through unanimous written consent to authorize "Gregg Ciarelli, as an employee of [BIPI] and in support of the U.S. Business Unit Ethical Pharmaceuticals," to execute and file contracts with vendors having a value less than \$250,000. (BIC/BIPI Fauci Exhibit 62) The Roxane Board of Directors granted similar authority to Mike Leonetti, also "as an employee of [BIPI]." (BIC/BIPI Fauci Exhibit 63)

BIC and BIPI's Reply: The Government's response does not create a disputed issue of fact material to BIC and BIPI's motion for summary judgment. The Government does not dispute, and its additional facts do not contradict, that in accordance with its bylaws and Delaware law, Roxane's Board acted through unanimous written consent, in lieu of meetings, to choose officers, directors, a chairman of the board, and to transact other company business or that Roxane maintained written records of the Board's bylaws and unanimous consents. As the Government does not dispute the substance of this statement of fact, it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). This paragraph sets forth material facts because it shows management and control of Roxane by its own board of directors, that the board functioned appropriately and that Roxane maintained corporate formalities, facts that indicate that Roxane operated as an independent company.

BIC and BIPI do not dispute that Mr. Berkle's deposition testimony contains the quoted language. The Government's quotations, however, are selective and incomplete; the entirety of the deposition is the best evidence of its contents. Mr. Berkle repeatedly stated that he was unable to recall details about Roxane's Board. (Tab 90, 10/31/08 Berkle Dep. 53-54) Further, Mr. Berkle's testimony that the Roxane Board did not meet does not mean it was not fully-functioning. As described in ¶¶ 21-29, Roxane's Board conducted all of the functions expected by a Board and acted through unanimous written consents, which is explicitly permitted by Roxane's bylaws and

Delaware law. (*See* 8 Del. Gen. Code § 141(f), Tab 42, Roxane Unanimous Consents, Bylaws of Roxane Laboratories, Inc. at BOEH04600229-247) As the Roxane Board appropriately functioned through unanimous written consents in accordance with its bylaws and Delaware law, Mr. Berkle's statements regarding his faded recollection are immaterial to BIC and BIPI's motion for summary judgment.

BIC and BIPI do not dispute that Professor Macey testified as quoted. The fact that Roxane respected corporate formalities as do most other companies supports that Roxane operated consistently with other independent companies. This is exactly why courts look to see if boards follow formalities: because the absence of such formalities is an indicator that the company is not independent. *InterGen N.V. v. Grina*, 344 F.3d 134, 149 (1st Cir. 2003). Thus, Professor Macey's testimony underscores that Roxane's Board followed "the most important facets" of "corporate formalities," namely "board composition, board processes and methods," which indicates that Roxane acted as an independent company. (BIC/BIPI Fauci Ex. 61, 5/20/09 Macey Dep. 292-94) BIC and BIPI object to and dispute the Government's statement that "Roxane has not offered any evidence to establish who created the unanimous written consents, nor whether or not they were prepared by counsel" because it is immaterial. The Government has provided no basis on which to call into question the legal validity of the unanimous written consents. They were created in accordance with Delaware law and Roxane bylaws and produced from Roxane's files as kept in the ordinary course of business.

BIC and BIPI dispute that the Roxane Board's unanimous written consents were made "at times merely to confirm or formally authorize decisions that had already been made by BIC and/or BIPI." This fact is not supported by the Government's proffered evidence. BIC and BIPI incorporate their Replies to ¶¶ 4, 27.

BIC and BIPI do not dispute that the Roxane Board authorized Gregg Ciarelli and Mike Leonetti to “execute and file contracts with vendors,” but dispute that this fact is material to BIC and BIPI’s motion for summary judgment. Because the Roxane Board authorized Messrs. Ciarelli and Leonetti to act on Roxane’s behalf, any action they took in executing and filing contracts related to Roxane products was done on behalf of Roxane and cannot be imputed to BIPI. (BIC/BIPI Fauci Ex. 62, 2/18/99 RLI Unanimous Written Consent of Directors; BIC/BIPI Fauci Ex. 63, 5/28/99 RLI Unanimous Written Consent of Directors) Moreover, the Board’s action is consistent with the facts that Mr. Ciarelli and Mr. Leonetti at this time had been given supervisory high-level roles relating to Roxane’s brand and branded generic drugs and were responsible for departments that were being consolidated into a centralized service function. (See BIC and BIPI’s Reply to SOF ¶¶ 2, 51; Tab 98, 5/19/09 Macey Dep. 159-62)

23. Roxane’s Board approved its bylaws. (Tab 42, BOEH04600226-47 (Roxane Unanimous Consents))

United States’ Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (See *supra* United States’ Response to Paragraph 22)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. See L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). This paragraph sets forth material facts because it shows management and control of Roxane by its board of directors, that the Board functioned appropriately and that Roxane maintained corporate formalities, facts that indicate that Roxane operated as an independent company. BIC and BIPI also incorporate their Reply to ¶ 22.

24. Roxane's Board approved financial reports and budgets. (Tab 42, BOEH04600159-67, BOEH04600197-06, BOEH04600254-63, BOEH04600302-06, BOEH04600330-39, BOEH04600363-68, BOEH04600392-97, BOEH04600430-35, BOEH04600465-77, BOEH04600609-14 (Roxane Unanimous Consents))

United States' Response: The United States does not dispute that at times the Roxane Board approved financial reports and budgets through "unanimous written consent." Further answering, the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). This paragraph sets forth material facts because it shows management and control of Roxane by its board of directors, that the Board functioned appropriately and that Roxane maintained corporate formalities, facts that indicate that Roxane operated as an independent company. BIC and BIPI also incorporate their Reply to ¶ 22.

25. Roxane's Board approved dividend payments to its parent company, BIC. (Tab 42, BOEH04600117-21, BOEH04600292-94, BOEH04600326-28, BOEH04600413-15 (Roxane Unanimous Consents))

United States' Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). This paragraph sets forth material facts because it shows management and control of Roxane by its board of directors, that the Board functioned appropriately and that Roxane

maintained corporate formalities, facts that indicate that Roxane operated as an independent company. BIC and BIPI also incorporate their Reply to ¶ 22.

26. Roxane's Board approved decisions to file law suits. (Tab 42, BOEH04600151-54 (Roxane Unanimous Consents))

United States' Response: The United States does not dispute that the Roxane Board approved the decision to file the lawsuit specified in the documents referenced at Tab 42. Further answering, the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). This paragraph sets forth material facts because it shows management and control of Roxane by its board of directors, that the Board functioned appropriately and that Roxane maintained corporate formalities, facts that indicate that Roxane operated as an independent company. BIC and BIPI also incorporate their Reply to ¶ 22.

27. Roxane's Board approved decisions to enter co-promotion agreements, and to acquire and divest drugs. (Tab 42, BOEH04600248-52, BOEH04600369-74, BOEH04600375- 77 (Roxane Unanimous Consents))

United States' Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22) Further answering, the Roxane Board of Directors' unanimous written consent authorizing the divestiture of the pain/palliative care products was dated September 28, 2001. Tab 42, at BOEH04600369 - BOEH04600371. The decision that Roxane would divest the pain/palliative care products was actually made in May 2000, at a joint meeting of the Boards of Directors of BIC and BIPI. (BIC/BIPI Fauci Exhibit 8, at BICJURIS0179-80) At another joint meeting of the BIC/BIPI Boards of Directors on June 21, 2001, Mr. Berkle reported that efforts were underway to out-license Roxane's pain and addiction products, and that offers had been received in excess of \$200 million. (BIC/BIPI Fauci Exhibit 64, at BICJURIS0122)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement

required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). This paragraph sets forth material facts because it shows management and control of Roxane by its board of directors, that the Board functioned appropriately and that Roxane maintained corporate formalities, facts that indicate that Roxane operated as an independent company. BIC and BIPI also incorporate their Reply to ¶ 22.

The Government’s additional facts and statements do not controvert, and are immaterial to, BIC and BIPI’s motion for summary judgment. BIC and BIPI do not dispute that the Roxane Board’s Unanimous Written Consent authorized the sale of the pain/palliative care products to Elan Pharma International, Limited, and was dated September 28, 2001. (Tab 42, Roxane Unanimous Consents at BOEH04600369-374) BIC and BIPI dispute that the decision to divest the pain/palliative care products was made in May 2000, at a joint meeting of the Boards of Directors of BIC and BIPI. Rather, the minutes of the joint meeting indicate that the divestiture was merely a topic of discussion. (BIC/BIPI Fauci Ex. 8, 5/15/00 BIC/BIPI Board of Directors Meeting Minutes at BICJURIS0179-180) The minutes reflect that “U.S. management, following discussion with the board, have approved a restructuring,” and that “[a]lternatives will be considered regarding selling the pain/palliative care business,” but no board resolution was made adopting any decisions regarding the divestiture. Additionally, the minutes point out that the decision to implement the restructuring was “deferred pending further developments in the lawsuit regarding MARINOL®.” (*Id.*) This sort of high-level reporting is within the normal range of information on which a parent company would be updated. (Tab 98, 5/19/09 Macey Dep. 131 (noting that it is “standard practice for a parent corporation to monitor and oversee its subsidiaries’ operations” and “to set high level policy and strategy at a subsidiary.”)) Ultimately, however, it was the Roxane Board of Directors,

not BIC's Board of Directors, that approved the sale by entering unanimous written consents, approving the sale to Elan Pharma International, Limited. (Tab 42, Roxane Unanimous Consents at BOEH04600369-374)

BIC and BIPI do not dispute that at the June 21, 2001 joint meeting of the BIC and BIPI Boards of Directors, Mr. Berkle reported that efforts were "underway to out-license the Roxane pain and addiction products," and that two offers had "been received in excess of \$200 million." (BIC/BIPI Fauci Ex. 64, 6/21/01 Joint Annual Board Meeting Minutes at BICJURIS0122) BIC and BIPI dispute that this additional fact is material to BIC and BIPI's motion for summary judgment. This sort of high-level reporting is within the normal range of information on which a parent company would be updated. (Tab 98, 5/19/09 Macey Dep. 131 (noting that it is "standard practice for a parent corporation to monitor and oversee its subsidiaries' operations" and "to set high level policy and strategy at a subsidiary.")) Furthermore, at no time during the June 21, 2001 BIC/BIPI joint board meeting did the board make any resolutions regarding or approving sales or licensing of Roxane's pain and addiction products. (BIC/BIPI Fauci Ex. 64 at BICJURIS0122) Those decisions were made by Roxane's Board of Directors. (Tab 42, Roxane Unanimous Consents (sale to Elan) at BOEH04600117-247, BOEH04600369; license to Ceber Pharmaceuticals, Inc. for certain addiction products at BOEH04600117-247, BOEH04600375)

28. In 2005, Roxane's Board approved of the decision to restructure the company into two separate corporations, one for sales and marketing, and one for manufacturing. (Tab 42, BOEH04600504-07, BOEH04600521-29, BOEH04600533-36, BOEH04600538-44 (Roxane Unanimous Consents))

United States' Response: Undisputed, except that the United States disputes that this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States' Response to Paragraph 22)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement

required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). This paragraph sets forth material facts because it shows management and control of Roxane by its board of directors, that the Board functioned appropriately and that Roxane maintained corporate formalities, facts that indicate that Roxane operated as an independent company. BIC and BIPI also incorporate their Reply to ¶ 22.

29. Roxane’s Board appointed officers. (Tab 42, BOEH04600159-67 (1996); BOEH04600197-06 (1997), BOEH04600207-09 (1997); BOEH04600254-63 (1998); BOEH04600267 (1998); BOEH04600302-06 (1999); BOEH04600330-33 (2000); BOEH04600363-68 (2001); BOEH04600392-97 (2002); BOEH04600382-85 (2002); BOEH04600430-35 (2003); BOEH04600465-77 (2004); BOEH04600609-14 (2005) (Roxane Unanimous Consents))

United States’ Response: Undisputed, except that the United States disputes this paragraph is material to whether or not Roxane operated as an independent company. (*See supra* United States’ Response to Paragraph 22)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). This paragraph sets forth material facts because it shows management and control of Roxane by its board of directors, that the Board functioned appropriately and that Roxane maintained corporate formalities, facts that indicate that Roxane operated as an independent company. BIC and BIPI also incorporate their Reply to ¶ 22.

30. Gerald Wojta was President and COO of Roxane until 1997. Following Wojta’s departure, Werner Gerstenberg served as President and COO of Roxane from 1997 until 2002. Roxane’s Board then appointed Robert Fromuth as President and COO, who held that position from 2002 until the 2005 split of Roxane. (Tab 38, RLI-AWP-00000058-67, RLI-AWP- 00000016-58, RLI-AWP-00000001-16 (Roxane Corporate Data); Tab 42, BOEH04600207-09, BOEH04600382-85 (Roxane Unanimous Consents))

United States’ Response: Undisputed. Further answering, Mr. Gerstenberg also served as the President and Chief Executive Officer of BIC during the relevant timeframe. (*See, e.g.*, BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 42:2 - 42:12; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 47:7 - 48:11, 219:20 - 220:10; BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 17:7 - 18:14; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 55:22 - 57:16) Mr. Fromuth replaced Mr. Gerstenberg as President and Chief Operating Officer of Roxane in April 2002, due to Mr. Gerstenberg’s “multiple executive responsibilities” at Boehringer Ingelheim and the fact that it was deemed “in the best interests of [Roxane] to have a Chief Operating Officer on site.” (Tab 42, at BOEH04600382-85)

Mr. Gerstenberg’s offices were at BIC and BIPI’s corporate headquarters in Connecticut, and Boehringer Ingelheim and Roxane employees regarded Mr. Gerstenberg as the President of BIC and reported to him in that capacity. (*See, e.g.*, BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.), at 42:2 - 42:12; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 47:7 - 48:11, 219:20 - 220:10; BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.), at 17:7 - 18:14; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 55:22 - 57:16) For example, Mr. Russillo (who supervised Roxane’s multi-source marketing) testified that he reported to Mr. Gerstenberg “in his role as president and CEO of BIC.” (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 29:8 - 30:10, 204:1 - 204:7, 205:19 - 207:2) The evidence supports the conclusion that Mr. Russillo reported to Mr. Gerstenberg as CEO of BIC for several reasons. First, Mr. Russillo testified that he reported to Mr. Gerstenberg both when Mr. Russillo was acting as the Chief Operating Officer of Ben Venue Labs, and when Mr. Russillo was supervising Roxane’s multi- source marketing. (*Id.*) Mr. Russillo did so even though there is no evidence that Mr. Gerstenberg was ever an officer of Ben Venue Labs. Second, Mr. Russillo continued to report to Mr. Gerstenberg through 2003, *after* Mr. Gerstenberg had been replaced as President of Roxane but when Mr. Gerstenberg was still serving as President of BIC. (*Id.*) Third, Mr. Russillo testified that he reported to Martin Carroll as President of BIC, after Mr. Carroll replaced Mr. Gerstenberg in that role, even though Mr. Carroll was not an officer at Roxane. (*Id.*; *see also* BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 31:11 - 32:10.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI dispute that the Government’s additional statements are material to BIC and BIPI’s motion for summary judgment or the Government’s direct liability or veil-piercing claim against them because they do not relate to setting or reporting AWP’s for any Subject Drugs and they do not demonstrate that BIC or BIPI pervasively controlled or acted with fraudulent purpose with regard to Roxane.

Although immaterial, BIC and BIPI do not dispute that Werner Gerstenberg served as CEO of BIC during the relevant timeframe until his retirement in December 2002. (Tab 124, Roxane Corporate Data Sheets at RLI-AWP-00000012-015) The fact that Mr. Gerstenberg served as both President and CEO of BIC and President and COO of Roxane is within the norm and completely appropriate. *See Bestfoods*, 524 U.S. at 69; *see also C.M. Corp.*, 631 F.2d at 539 (noting that overlap in officers and directors is insufficient to invoke the veil-piercing doctrine because it “exist[s] in most parent and subsidiary relationships.”) (citation and quotation marks omitted). BIC and BIPI do not dispute that the Government correctly quoted the March 14, 2002 Unanimous Written Consent of the Roxane Board of Directors. (Tab 42, Roxane Unanimous Consents at BOEH04600382-85) BIC and BIPI dispute that the replacement of Mr. Gerstenberg by Mr. Fromuth is material to BIC and BIPI’s motion for summary judgment.

BIC and BIPI do not dispute that Mr. Gerstenberg’s offices were located in Connecticut or that certain employees regarded Mr. Gerstenberg as the President and CEO of BIC and reported to him in that capacity. BIC and BIPI dispute the implication that Roxane employees solely “regarded Mr. Gerstenberg as the President of BIC and reported to him in that capacity.” This fact is not supported by the Government’s proffered evidence. First, because Mr. Gerstenberg was President and CEO of BIC, certain people reported to him in that capacity. (Tab 90, 10/31/08 Berkle Dep. 28, 262 (Mr. Berkle, as Executive Vice President of BIPI, reported to Mr. Gerstenberg as CEO of BIC); Tab 89, 1/27/05 Berkle Dep. 24, 42 (Jerry Wojta, when President and COO of Roxane, ultimately reported to Werner Gerstenberg as “CEO and head of BIC.”)) Second, others reported to Mr. Gerstenberg in his capacity as President and COO of Roxane. (*See, e.g.*, Tab 115, Roxane Organization Chart) For instance, Mr. Russillo, who at the end of 1998 was responsible for the Roxane multisource business testified that if he consulted Mr. Gerstenberg regarding Roxane

business, Mr. Gerstenberg “would have been acting as the president of Roxane.” (Tab 106, 1/18/09 Russillo Dep. 24 26-27, 98, 174-75; *see also* BIC/BIPI SOF at ¶¶ 60-62, 71) However, when acting in his capacity as President and COO of Ben Venue Laboratories, Inc., Mr. Russillo reported to Werner Gerstenberg in Mr. Gerstenberg’s capacity as President and CEO of BIC. (Tab 32, Jan. 1998 Organization Chart; Tab 33, Jan. 2000 Organization Chart)

BIC and BIPI dispute the Government’s implication that Mr. Russillo’s testimony indicates that he reported to Mr. Gerstenberg “in his role as president and CEO of BIC” for all matters. When asked specifically to whom he reported regarding Roxane marketing decisions, and in what capacity he consulted Mr. Gerstenberg regarding Roxane multisource price increases, Mr. Russillo’s undisputed testimony is that in those instances, Mr. Gerstenberg was acting as President and COO of Roxane. (Tab 106, 1/8/09 Russillo Dep. 28 (“Mr. Gerstenberg was the president of Roxane Laboratories. As such, I had an obligation to keep him informed as to what was going on.”), 173-75) The Government’s reference to Mr. Russillo’s later testimony where he responded “yes” to more general questions regarding whether he reported to Mr. Gerstenberg “in his role as president and CEO of BIC” and whether he was directed by Mr. Gerstenberg in that role to take over management of Roxane’s multisource business does not contradict his testimony that with respect to Roxane marketing decisions he consulted Mr. Gerstenberg as the President and COO of Roxane. As the Government recognizes in its Response to this statement of fact, at the time Mr. Russillo became the Head of Roxane’s Multisource products, Mr. Russillo was the President and COO of a separate BIC subsidiary, Ben Venue Laboratories, Inc., and in that role he would have reported to Mr. Gerstenberg as the President and CEO of BIC. (Tab 32, Jan. 1998 Organization Chart; Tab 33, Jan. 2000 Organization Chart) In addition, it makes sense that Mr. Gerstenberg was acting in his role as President of BIC when he directed the President and COO of another BIC subsidiary to take on a

high-level role at a different subsidiary. Further, Mr. Russillo remained President and COO of Ben Venue until he left the company and therefore would have continued to report to Mr. Gerstenberg after he stepped down as President and COO of Roxane, and then Mr. Carroll after Mr. Gerstenberg in their capacities as the President and CEO of BIC. And even in his Roxane role, there may have been higher level strategy or organizational issues that Mr. Russillo discussed with Mr. Gerstenberg and Mr. Carroll in their role at the parent company. Thus, all of the points raised by the Government merely reflect that both Mr. Russillo and Mr. Gerstenberg wore more than one “hat” and had different reporting relationships in their different capacities.

Moreover, even if Mr. Russillo in his role as Head of Roxane Multisource reported to Mr. Gerstenberg after 2003 and Mr. Carroll after that in their capacities as the President and CEO of BIC, this is immaterial to BIC and BIPI’s motion for summary judgment and the Government’s claims against them as the Government points to no evidence that either Mr. Gerstenberg or Mr. Carroll were involved in any AWP or other pricing or marketing decision for any Subject Drug during that timeframe.

(b) Roxane Maintained Separate Financial Records

31. Roxane’s finances were accounted for separately and independently from its parent and affiliates, and Roxane kept its own separate financial records and statements. (Tab 15, McIntyre Dep. 202; Tab 43, BOEH04600203-05 (1996 Commentary); Tab 44, BOEH02541150- 69 at 54, 60 (Commentary 1997 Actual); Tab 45, BOEH02541103-22 at 06, 12 (Commentary 1998 Year End Actual); Tab 46, BOEH02584571-97 at 76, 94 (Commentary 1999 Budget 1999 Actual); Tab 47, BOEH02687778-03 at 81, 02 (Commentary 2000 Target 2000 Actual); Tab 48, BOEH02675446-72 at 49, 71 (Commentary To The Financial Statements For Year End 12/31/01); Tab 49, BOEH00147729-58 at 33, 57 (2002 Year-End Financial Commentary); Tab 50, BOEH02675333-62 at 37, 53 (Roxane Labs, Inc. Year End 2003 & Commentary); Tab 51, BOEH04295701-32 at 25, 29 (Roxane Labs, Inc. Year End 2004 & Commentary); Tab 52, BOEH02522567-99 at 91, 95 (Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc. 2005 Year End Commentary))

United States’ Response: The United States does not dispute that Boehringer Ingelheim kept separate financial records for Roxane, including Profit and Loss Statements and year-end Balance Sheets. Further answering, beginning in 2001, accounting services for Roxane were performed, at

least in part, by BIPI personnel. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 33:17 - 34:15)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Disputed that BIPI personnel performed accounting services for Roxane beginning in 2001, as the Government’s proffered evidence does not support that alleged fact. The Government’s evidence only indicates that “[a]fter 2001, some of the accounting was centralized with BIPI as a central service and . . . Roxane was charged back for that service.” (BIC/BIPI Fauci Ex. 45, 2/26/09 McIntyre Dep. 34) It indicates only that a central entity performed services for both Roxane and BIPI, not that BIPI, or any BIPI personnel, performed accounting functions for Roxane. (*Id.*) Furthermore, the Government’s proffered evidence shows that even during that time, Roxane maintained its own accounting records. (*Id.*) In addition, BIC disputes that the Government’s additional fact is material to BIC’s motion or the Government’s direct liability and veil-piercing claims against it because it relates solely to BIPI.

32. During the relevant time period, a separate entity within the BIC corporate group, BI Services Center, Inc. (“BISC”) provided transactional financial services for BIC’s subsidiaries, such as accounts payable, accounts receivable, payroll, and customer service. (Tab 15, McIntyre Dep. 37-38, 41)

United States’ Response: Undisputed. Further answering, other corporate functions such as finance and administration, legal, and information technology were performed by BIPI personnel. (BIC/BIPI Fauci Exhibit 3, at RLI-AWP-00107354; BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 37:9 - 40:22)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement

required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

BIC and BIPI do not dispute that, at certain times, finance and administration, legal and information technology functions were performed as a shared service by BIPI, but disputes that each of these services was provided to Roxane by BIPI for the entire relevant timeframe. (*See* BIC and BIPI’s Reply to SOF ¶ 2) Further, the Government’s proffered evidence demonstrates that Roxane was charged back for those services. (BIC/BIPI Fauci Ex. 45, 2/26/09 McIntyre Dep. 40) In addition, BIC disputes that the Government’s additional fact is material to BIC’s motion or the Government’s direct liability and veil-piercing claim against it because it relates solely to BIPI.

33. As part of the centralized financial services, BIC and its subsidiaries used a zero balance cash management system. Each legal entity had its own bank account, and at the end of each day, the money from each entity’s account was swept into a combined account so it could be invested on behalf of the entities. Records were kept tracking the amount that each individual affiliate contributed or withdrew from the investment account. (*Id.* 162-163).

United States’ Response: Undisputed except the phrase “had its own bank account” is ambiguous as used in this sentence, and there is no evidence to support a finding that Roxane kept its cash in a separate bank account from other Boehringer Ingelheim entities. Hermann Tetzner, who served as BIC’s Chief Financial Office, testified that cash at Boehringer Ingelheim’s United States companies was swept daily into “a corporate cash pool controlled by Boehringer Ingelheim in Germany.” (BIC/BIPI Fauci Exhibit 6 (10/19/2004 Tetzner Dep.), at 12:16 - 12:23, 175:20 - 177:2)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Disputed that Hermann Tetzner testified as quoted, as the Government's proffered evidence does not contain the quote "a corporate cash pool controlled by Boehringer Ingelheim in Germany." In addition, while BIC and BIPI contend the evidence supports that Roxane had an individual account where cash was kept (Tab 101, 2/26/09 McIntyre Dep. 162-63), it is immaterial to BIC and BIPI's motion for summary judgment as the Government does not dispute that cash was tracked on a company-by-company basis.

34. Through the central cash management system established at the BISC, inter-company loans and short term advances to affiliates were made among BIC and its subsidiaries. The loans and advances were accounted for and tracked by the BISC through internal accounting records. (*Id.* 126-127, 160-162).

United States' Response: The United States does not dispute that loans were made among BIC and its subsidiaries.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). To the extent the Government's response is anything other than an unqualified admission, BIC and BIPI object to the Government's response because it is not clear what material facts, if any, it is disputing and because it provides no basis for its dispute.

35. For loans and advances, the borrowing company paid interest to the lending company at a rate of LIBOR plus .25%. (*Id.* 126-127).

United States' Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted

by opposing parties unless controverted by the statement required to be served by opposing parties.”).

(c) Roxane Was Sufficiently Capitalized at All Times

36. Roxane’s business consistently generated income and it maintained substantial retained earnings. Roxane never needed to use any funds from its capital stock or its additional paid-in capital, and the balances of each remained the same over time. Between 1995 - 2005, Roxane had an average annual net income of \$37,964,000. During that same period, it had average annual retained earnings of \$146,165,182. (Tab 42, BOEH04600164-67, BOEH04600102-06, BOEH04600258-63, BOEH04600305-06, BOEH04600335-36, BOEH04600367-68, BOEH04600396-97, BOEH04600434-35, BOEH0460046569-71, BOEH04600613-14 (Roxane Unanimous Consents))

United States’ Response: The United States does not dispute that Roxane’s business generated income throughout the relevant time period. The United States, however, does dispute that Roxane “maintained substantial retained earnings” throughout the time period. The United States further disputes that Roxane’s “average annual net income” or its “average annual retained earnings” are relevant to an evaluation of whether or not Roxane was sufficiently capitalized at any particular point in time, or is sufficiently capitalized now. As explained in greater detail below, Roxane’s retained earnings dropped dramatically in 2002, after Roxane received its first subpoena from the United States in August 2000, and following Roxane’s payment of an unbudgeted \$320 million “dividend” to BIC in November 2002. (BIC/BIPI Fauci Exhibit 109, at BIC JURIS 0920 (noting that the “planned dividend” was \$75 million versus the actual dividend of \$320 million); BIC/BIPI Fauci Exhibit 66; BIC/BIPI Fauci Exhibit 67, at BOEH04600434)

From 1996 until 2002, Roxane’s retained earnings grew annually, and in each year significantly exceeded Roxane’s total liabilities. (BIC/BIPI Fauci Exhibit 68 (year-end 1996), at BOEH04600205; BIC/BIPI Fauci Exhibit 69 (year-end 1997), at BOEH04600262; BIC/BIPI Fauci Exhibit 70 (year-end 1998), at BOEH04600306; BIC/BIPI Fauci Exhibit 108 (year-end 1999), at BOEH04600335; BIC/BIPI Fauci Exhibit 72 (year-end 2000 and 2001), at BOEH04600396; BIC/BIPI Fauci Exhibit 67 (year-end 2002), at BOEH04600434) Roxane’s retained earnings consistently exceeded total liabilities during this time period even though Roxane paid a \$41 million dividend to BIC in May 1999, and a \$50 million dividend to BIC in May 2000. (BIC/BIPI Fauci Exhibit 71; BIC/BIPI Fauci Exhibit 74) Roxane originally budgeted that its retained earnings for 2002 would be approximately \$402 million, against total liabilities of approximately \$144 million. (BIC/BIPI Fauci Exhibit 67, at BOEH04600434) However, after paying the \$320 million dividend to BIC in November 2002, Roxane’s actual retained earnings for year-end 2002 were slightly more than \$46 million, against total liabilities of over \$320 million. (*Id.*) As seen in the table below, 2002 was the first year since at least 1996 when Roxane’s total liabilities exceeded its retained earnings.

Year	Income	Retained Earnings	Total Liabilities
1996	\$ 39,134,000	\$131,677,000	\$ 81,037,000

1997	\$ 40,136,000	\$171,813,000	\$ 70,895,000
1998	\$ 41,153,000	\$212,966,000	\$ 61,789,000
1999	\$ 45,055,000	\$217,021,000	\$103,489,000
2000	\$ 42,324,000	\$219,521,000	\$157,563,000
2001	\$139,001,000	\$358,522,000	\$203,495,000
2002	\$ 7,601,000	\$ 46,121,000	\$320,927,000

Roxane's sale of its palliative care/pain products. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 198:2 - 199:18) The proceeds from the sale of these products were included in Roxane's \$139 million stated income for 2001. (*Id.*, at 212:5 - 214:1) The \$320 million dividend paid to BIC in November 2002 exceeded Roxane's combined income from 1997 through 2001, and was in addition to the \$41 and \$50 million dividends paid to BIC in 1999 and 2000. In total, from 1996 through 2002, Roxane earned approximately \$355 million in income, and paid \$411 million to BIC in dividends. (BIC/BIPI Fauci Exhibit 68 (year-end 1996), at BOEH04600205; BIC/BIPI Fauci Exhibit 69 (year-end 1997), at BOEH04600262; BIC/BIPI Fauci Exhibit 70 (year-end 1998), at BOEH04600306; BIC/BIPI Fauci Exhibit 108 (year-end 1999), at BOEH04600335; BIC/BIPI Fauci Exhibit 72 (year-end 2000 and 2001), at BOEH04600396; BIC/BIPI Fauci Exhibit 67 (year-end 2002), at BOEH04600434; BIC/BIPI Fauci Exhibit 66; BIC/BIPI Fauci Exhibit 71; BIC/BIPI Fauci Exhibit 74) Roxane's retained earnings remained significantly lower than its total liabilities through at least 2004. For example, Roxane's retained earnings in 2003 were approximately \$65 million, compared to total liabilities of \$258 million. (BIC/BIPI Fauci Exhibit 75) Retained earnings in 2004 were approximately \$51 million, compared to total liabilities of \$335 million. (BIC/BIPI Fauci Exhibit 76)

The United States does not dispute that from 1996 through 2005, Roxane's did not deplete funds from its "Capital Stock" of \$19,000, or its "Additional Paid-In Capital" of \$8,735,000. However, the United States disputes that this fact is material to evaluating whether Roxane was sufficiently capitalized at any particular point in time given that Roxane grew in size over time and by 2002, had total liabilities exceeding \$320 million.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). The Government provides no basis for disputing that Roxane maintained substantial

retained earnings and therefore that fact should be deemed admitted as well. Roxane's average net income and retained earnings are material as they establish Roxane's overall solid financial position during the relevant timeframe and support that it was able to independently generate substantial income over time and had sufficient capital to meet its obligations. The Government's additional facts do not controvert BIC and BIPI's statement of fact and are immaterial to BIPI as they relate solely to BIC. They are also immaterial to BIC's motion for summary judgment for the reasons discussed below.

The Government's implication that Roxane's payment of a \$320 million dividend in 2002 to BIC was related to a government subpoena received in 2000 is wholly unsupported by citations to any record evidence. The evidence the Government cites shows only that an unbudgeted \$320 million dividend was paid in 2002. It cites no evidence that the reason this dividend was paid related in any manner to the Government's 2000 subpoena and therefore the Government has failed to raise a genuine issue of fact on this point.

In fact, the Government's theory that the amount or timing of Roxane's 2002 dividend payment had any relation to the Government's 2000 subpoena is directly contradicted by the record evidence. Mr. McIntyre, Roxane's corporate representative, testified that the \$320 million dividend payment "had nothing to do with any litigation." (Tab 101, 2/26/09 McIntyre Dep. 200; Tab 129, Declaration of Frank Pomer in Support of Reply to the United States' Response to BIC and BIPI's Statement of Undisputed Material Facts in Support of Motion for Summary Judgment ("Pomer Declaration") at ¶ 12) Rather, the 2002 dividend payment was larger due to several business circumstances and reasons. First, in 2001, Roxane sold its palliative care portfolio of drugs to Elan Pharmaceuticals, resulting in a significant, unplanned \$175 million increase in income that year. (Tab 101, 2/26/09 McIntyre Dep. 196-97; Tab 129, Pomer Declaration at ¶ 11)

Second, there was a significant tax incentive for BIC to pay a dividend to its Canadian parent, Pharma (“Pharma Canada”), and subsequently to its German parent company, BIA (“BIA Germany”), prior to year-end 2002. More specifically, as Mr. Pomer, the corporate tax officer for BIC and its subsidiaries, explains, prior to 2002, BIC had not issued a dividend to its parent, Pharma Canada, mainly due to unfavorable tax consequences. Accordingly, no dividend had been distributed from Pharma Canada to BIA Germany. (Tab 129, Pomer Declaration at ¶ 6)

Because BIC was not paying dividends to Pharma Canada, it did not receive dividend payments on a regular basis from its operating subsidiaries, including Roxane. Instead, BIC chose to leave the bulk of the operating subsidiaries’ retained earnings at the subsidiary level. (*Id.*) However, in 2002, a provision of the new Canada-Germany tax treaty would impose a 16% German trade tax on any dividends paid by Pharma Canada to BIA Germany after 2002. Thus, if a dividend was going to be paid to BIA Germany, there was a significant tax incentive to distribute the dividend before the end of 2002 so that it would not be subject to the German trade tax. (*Id.* at ¶ 7)

In order for Pharma to pay a dividend to BIA Germany before the end of 2002, BIC had to distribute a roughly equivalent dividend to Pharma Canada. (*Id.* at ¶ 8) In preparation for making this dividend distribution to Pharma Canada, BIC’s operating subsidiaries, including Roxane, declared dividends to BIC. The 2002 dividends were larger than those paid in past years when BIC was not in turn distributing dividends to Pharma Canada as this was an opportunity for undistributed earnings for many years to be distributed to Pharma Canada and subsequently to BIA Germany prior to more significant tax liabilities being incurred. (*Id.*)

Roxane was not the only operating subsidiary to pay a larger dividend than in prior years. For example, in addition to Roxane’s \$320 million dividend to BIC, BIPI declared a \$475 million dividend when it had not paid any dividend to BIC since at least 1997, and BVL declared a \$250

million dividend, compared to prior dividends of \$57 million in 2000 and \$35 million in 1999.

(*Id.*) Thus, as Mr. McIntyre testified, the 2002 dividend was “a catch up.” (Tab 101, 2/26/09 McIntyre Dep. 196-200)

In addition, the Government’s attempt to imply an improper motive behind the 2002 dividend makes even less sense given that Roxane was aware of Government investigations into AWP’s by 1999 and some States, like Texas, had already brought lawsuits by 2000. (Tab 106, 1/8/09 Russillo Dep. 99; Tab 120, Gerstenberg Memo re Texas Lawsuit, BOEH01057049) Even the Government’s subpoena was issued in 2000, more than two years before the dividend payment was made.

In addition, the Government’s facts and discussion regarding Roxane’s amount of retained earnings and the relationship between its retained earnings and its liabilities before and after the dividend payment are misleading and immaterial and fail to create a disputed fact material to BIC and BIPI’s motion for summary judgment. More specifically, the Government’s focus on the reduction in Roxane’s retained earnings after the 2002 dividend is immaterial to whether Roxane was adequately capitalized; the fact that Roxane maintained higher retained earnings than necessary for its capitalization prior to 2002 is not evidence that its retained earnings in later years were too low. As the Government itself states, Roxane had retained earnings in the \$50-60 million range following the dividend payment. And the record is replete with evidence showing that Roxane was adequately capitalized and able to meet its obligations as they came due, even after paying the \$320 million dividend. (BIC/BIPI SOF at ¶¶ 37, 39-40, 95; Tab 129, Pomer Declaration at ¶ 6, 16)

In addition, the Government’s comparison of Roxane’s retained earnings pre and post the dividend payment and its statement that the dividend payment exceeded Roxane’s income from 1997-2001 are misleading. Roxane’s large retained earnings as of 2001 were an accumulation of many prior years’ net income because it was not paying dividends to its parent, BIC, on a regular

basis. (Tab 129, Pomer Declaration at ¶ 6) As the Government's own chart shows, by 1996, Roxane had more than \$131 million in retained earnings accumulated and had \$358 million in retained earnings by 2002, yet Roxane's yearly net income was generally in the \$40-45 million range. Thus it is clear that Roxane had not been distributing its earnings to its parent company on a regular basis for many years. (The reason it was not paying dividends on a regular basis was not because Roxane needed that level of retained earnings to be adequately capitalized, but for tax reasons.) (*Id.* at ¶¶ 6, 8) Thus, when tax issues allowed a dividend to be paid in 2002, it made sense that the dividend would be larger than its income for the past five years, because its retained earnings included earnings accumulated from many more than five years. (*Id.*; Tab 101, 2/26/09 McIntyre Dep. 196-97) For this same reason it is not meaningful to compare the relationship between retained earnings and liabilities in years where retained earnings were an accumulation of undistributed earnings for many past years to years where they were not.

The Government's comparison of retained earnings to "total liabilities" is also vague and misleading because the liabilities figure includes all short-term liabilities, which Roxane would not have included in determining whether it had sufficient capitalization. (Tab 129, Pomer Declaration at ¶ 15; *see also* Tab 130, Declaration of Boris J. Steffen in Support of Reply to the United States' Response to BIC and BIPI's Statement of Undisputed Material Facts in Support of Motion for Summary Judgment ("Steffen Decl.") at ¶¶ 4, 9 (short-term liabilities should be excluded from debt-to-equity ratio)) Roxane and its affiliates calculate their debt to equity ratios based upon the Proposed Treasury Regulations Section 1.163(j)-3, which provides the IRS' definitions and computation guidelines for determining debt-to-equity ratio. (*Id.*) Under those guidelines, short-term liabilities are excluded. (*Id.*) Roxane's balance sheet as of December 2002 lists a significant number of short term liabilities that Roxane would not have included in the liabilities figure used to

calculate its debt-to-equity ratio, including Trade Accounts Payable of \$17.7 million, Tax Provisions of \$15.3 million and Deferred Taxes of \$34.1 million. (*Id.*) Also, the category Other Provisions and Accruals, at \$59.7 million, likely contains a large portion of short-term obligations that would not be included in Roxane's debt-to-equity ratio calculations. (*Id.*)

Finally, the Government provides no reason why changes in Roxane's size or balance sheet impact the significance of its untouched capital stock and additional paid-in capital. The amount of shareholders' equity is the total of capital stock and additional-paid in capital, along with retained earnings. The fact that capital stock and additional paid-in capital are not encroached upon demonstrates that Roxane's liabilities never exceeded its assets in such a manner that it was necessary to use those funds to cover its debts. (Tab 99, 5/20/09 Macey Dep. 345-46)

37. Roxane always had sufficient working capital to pay for its day-to-day obligations, such as bills, vendors, employees, ingredients and raw materials. (Tab 15, McIntyre Dep. 192- 194).

United States' Response: The United States does not dispute that Roxane was able to pay its day-to-day obligations. However, the United States notes that in 2002, Roxane's total liabilities were over five times larger than its stockholders' equity (including retained earnings). Following Roxane's payment of the \$320 million dividend in 2002, Roxane was required to take out a new \$140 million loan from its corporate affiliate, and Roxane's total liabilities increased by almost \$120 million from 2001 to 2002. Roxane's total liabilities continued to exceed its stockholder's equity through at least 2004.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). BIC and BIPI dispute the Government's additional facts because they are unsupported by citations to the record as required Local Rule 56. Moreover, all of the Government's additional facts are immaterial to BIPI.

In addition, the Government's additional fact regarding the relationship between Roxane's liabilities and its equity are incorrect, misleading and immaterial. First this fact is immaterial to whether Roxane was adequately capitalized as the record is replete with evidence showing that Roxane was adequately capitalized and able to meet its obligations as they came due, even after paying the \$320 million dividend. (BIC/BIPI SOF at ¶¶ 37, 39-40, 95; Tab 129, Pomer Declaration at ¶¶ 6, 16) BIC and BIPI dispute any implication that the 2002 dividend payment was inappropriate or motivated by any improper purpose. No evidence supports this implication; rather it is contradicted by the record evidence, which demonstrates that the amount and timing of the payment were based on legitimate business circumstances and reasons. (*See* BIC and BIPI's Reply to SOF ¶ 36)

Moreover, the Government's statement that Roxane's liabilities were over five times larger than its equity is incorrect and misleading as the "total liabilities" figure the Government uses includes short-term liabilities that should have been excluded and would have reduced the ratio calculated by the Government. (Tab 129, Pomer Declaration at ¶ 15; *see also* Tab 130, Steffen Decl. at ¶¶ 4, 9 (short-term liabilities should be excluded from debt-to-equity ratio)) Roxane and its affiliates calculate their debt to equity ratios based upon the Proposed Treasury Regulations Section 1.163(j)-3, which provides the IRS' definitions and computation guidelines for determining debt-to-equity ratio. (*Id.*) Under those guidelines, short-term liabilities are excluded from the calculation. (*Id.*) Roxane's balance sheet as of December 2002 lists a significant number of short term liabilities that Roxane would not have included in its debt-to-equity ratio calculation, including Trade Accounts Payable of \$17.7 million, Tax Provisions of \$15.3 million and Deferred Taxes of \$34.1 million. (*Id.*) Also, the category Other Provisions and Accruals, at \$59.7 million, likely contains a

large portion of short-term obligations that would not be included in Roxane's debt-to-equity ratio calculations. (*Id.*)

BIC and BIPI further dispute that Roxane's loan from a corporate affiliate is material to its financial position. It is common practice for companies whose assets are not liquid to obtain loans from affiliates in order to pay a dividend in cash. Roxane's inter-company loan does not evidence that Roxane had insufficient assets to pay the \$320 million dividend in 2002; rather, Roxane obtained the loan in order to pay the dividend in cash. (Tab 101, 2/26/09 McIntyre Dep. 139-41)

38. Roxane's Board of Directors authorized dividend payments to be made to its parent corporation, BIC, based on the amount of its retained earnings and income. The amount of Roxane's dividend payment would increase when Roxane's income increased. (*Id.* 190-191; (Tab 42, BOEH04600117-21, BOEH04600292-94, BOEH04600326-28, BOEH04600413-15 (Roxane Unanimous Consents))

United States' Response: The United States does not dispute that Roxane's Board of Directors authorized dividend payments to be paid to BIC. The paragraph is otherwise disputed, and is not supported by the cited authority. Further answering, Roxane paid no dividends to BIC from 1996 through 1998. Roxane paid dividends in 1999 and 2000 which roughly approximated its total income for those years. In 2002, Roxane deviated from its past practice and paid a dividend of \$320 million, an amount greater than Roxane's total net income for the *preceding five years*. As noted *supra* in the United States' Response to Paragraph 36, this dividend was paid *after* Roxane received its first subpoena from the United States.

Moreover, the \$320 million dividend paid to BIC in November 2002 was inconsistent with Boehringer Ingelheim guidelines. At Boehringer Ingelheim, it was considered appropriate for a subsidiary such as Roxane to pay a dividend if its debt to equity ratio was less than 1.5 to 1. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 210:4 - 211:4) In 2002, following payment of the \$320 million dividend to BIC, Roxane's total liabilities were over *five times* greater than total equity.

BIC and BIPI's Reply: The cited documents demonstrate that Roxane paid larger dividends when its income was greater. The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing

parties.”). BIC and BIPI dispute the Government’s additional facts that are not supported by citations to the record as required by Local Rule 56. Moreover, all of the Government’s additional facts are immaterial to BIPI as they relate solely to BIC.

In addition, the Government’s additional facts regarding Roxane’s dividend payments and the relationship between Roxane’s liabilities and its equity are incorrect, misleading and immaterial. First this fact is immaterial to whether Roxane was adequately capitalized as the record is replete with evidence showing that Roxane was adequately capitalized and able to meet its obligations as they came due, even after paying the \$320 million dividend. (BIC/BIPI SOF at ¶¶ 37, 39-40, 95; Tab 129, Pomer Declaration at ¶¶ 6, 16)

BIC and BIPI dispute any implication that the 2002 dividend payment was inappropriate or motivated by the Government’s 2000 subpoena. No evidence supports this implication; rather it is contradicted by the record evidence, which demonstrates that the amount and timing of the payment were based on legitimate business circumstances and reasons. (*See* BIC and BIPI’s Reply to SOF ¶ 36) In addition, the Government’s statement that the 2002 dividend was greater than Roxane’s income for the preceding five years is misleading, as it fails to take into account that Roxane had accumulated undistributed earnings for more than five years, which it had not been previously paid to BIC through a dividend. (*See* BIC and BIPI’s Reply to SOF ¶ 36) Thus, this fact is immaterial to BIC and BIPI’s motion for summary judgment.

BIC and BIPI also dispute that Roxane’s 2002 dividend to BIC was inconsistent with Boehringer Ingelheim guidelines. The Government misinterprets the Boehringer Ingelheim guideline and uses debt-to-equity ratio computation that is different from that used by Roxane and its affiliates for purposes of the Boehringer Ingelheim dividend guideline. The Boehringer Ingelheim guideline applied to the U.S. subsidiaries on a consolidated basis, rather than to the individual debt-

to-equity ratios of each subsidiary. (Tab 129, Pomer Declaration at ¶¶ 13-14) Therefore, a dividend was considered proper when the combined debt-to-equity ratio of the U.S. subsidiaries was less than 1.5 to 1. (*Id.*) BIC and BIPI also dispute that Roxane's liability were over five times larger than its equity as it is incorrect and misleading, and thus immaterial, as the "total liabilities" figure the Government uses includes short-term liabilities that should have been excluded and would have reduced the ratio calculated by the Government. (*Id.* at ¶ 15; *see also* Tab 130, Steffen Decl. at ¶¶ 4, 9 (short-term liabilities should be excluded from debt-to-equity ratio)) More specifically, for purposes of the dividend guideline, Roxane and its affiliates calculate their debt to equity ratios based upon the Proposed Treasury Regulations Section 1.163(j)-3, which provides the IRS' definitions and computation guidelines for determining debt-to-equity ratio. (*Id.*) Under those guidelines, short-term liabilities are excluded from the calculation. (*Id.*) Roxane's balance sheet as of December 2002 lists a significant number of short term liabilities that Roxane would not have included in its debt-to-equity ratio calculation, including Trade Accounts Payable of \$17.7 million, Tax Provisions of \$15.3 million and Deferred Taxes of \$34.1 million. (*Id.*) Also, the category Other Provisions and Accruals, at \$59.7 million, likely contains a large portion of short-term obligations that would not be included in Roxane's debt-to-equity ratio calculations. (*Id.*)

39. Roxane continued to be sufficiently capitalized after all of its dividend payments, as indicated by the company's continued positive retained earnings and positive working capital. (Tab 15, McIntyre Dep. 192; *see also* ¶ 36, *supra*.)

United States' Response: Disputed. As noted *supra*, Roxane's total liabilities were over five times greater than its total equity at year-end 2002, and Roxane's total liabilities continued to greatly exceed total equity through at least 2004. (*See supra* United States' Responses to Paragraphs 36 - 38).

Further answering, prior to 2002, Roxane's debt to equity ratio was consistently less than one (that is, Roxane's liabilities were less than total equity). (*See supra* United States' Response to Paragraph 36). This is consistent with the debt to equity ratios observed at many of Roxane's competitors. Specifically, the United States was able to obtain financial information for six companies Roxane regarded as competitors. Of those six, four companies consistently had debt to

equity ratios less than 1.5 to 1. (BIC/BIPI Fauci Exhibit 110 (Declaration of Patrick Ormond), ¶¶ 17 - 19)

Roxane's debt to equity ratio grew to in excess of 5 to 1 only after Roxane paid a \$320 million dividend to BIC in November 2002. Payment of this dividend left Roxane significantly less capitalized than it had been from 1996 through 2001, and significantly less capitalized than many of its competitors. (*See supra* United States' Response to Paragraph 36; BIC/BIPI Fauci Exhibit 110 (Declaration of Patrick Ormond), ¶¶ 17 - 19). Moreover, payment of this dividend was in apparent disregard of Boehringer Ingelheim's guidelines regarding dividends. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 210:4 - 211:4)

BIC and BIPI's Reply: The Government's response does not create a disputed issue of fact material to BIC and BIPI's motion for summary judgment. BIC and BIPI object to the Government's response to the extent it is based on the Declaration of Patrick Ormond, which was submitted after the close of discovery and with respect to which BIC and BIPI did not have the opportunity to conduct discovery. The Government's additional facts are immaterial because they do not provide a basis to dispute that Roxane was sufficiently capitalized after its dividend payments. While, as discussed below, BIC and BIPI dispute the Government's characterization of its financial position and the validity of its comparisons to Roxane's competitors, even if Roxane had less retained earnings and a higher debt to equity ratio that was higher than its competitors after the \$320 million dividend, this by itself does not establish that Roxane was inadequately capitalized. The fact that Roxane maintained higher retained earnings and a lower debt-to-equity ratio than necessary for its capitalization prior to 2002 does not establish that its retained earnings in later years were too low or its debt-to-equity ratio too high. On the contrary, the undisputed evidence is that even after the dividend payment, Roxane had substantial retained earnings and positive working capital, was able to pay its debts as they came due and continued to independently generate income. (BIC/BIPI SOF at ¶¶ 37, 39-40, 95; Tab 129, Pomer Declaration at ¶¶ 6, 16) In other words, Roxane was adequately capitalized. In fact, Roxane remains in business today and continues to generate income and meet its obligations. (Tab 129, Pomer Declaration at ¶ 16)

Moreover, BIC and BIPI dispute the Government's statement that Roxane's liabilities were over five times larger than its equity at the end of 2002 as it is incorrect and misleading. The "total liabilities" figure the Government uses includes short-term liabilities that should have been excluded and would have reduced the ratio calculated by the Government. (*Id.* at ¶ 15; *see also* Tab 130, Steffen Decl. at ¶¶ 4, 9 (short-term liabilities should be excluded from debt-to-equity ratio)) Proposed Treasury Regulations Section 1.163(j)-3 provides the IRS' definitions and computation guidelines for determining debt-to-equity ratios. (*Id.*) Under those guidelines, short-term liabilities are excluded from the calculation. (*Id.*) Roxane's balance sheet as of December 2002 lists a significant number of short term liabilities that Roxane would not have included in its debt-to-equity ratio calculation, including Trade Accounts Payable of \$17.7 million, Tax Provisions of \$15.3 million and Deferred Taxes of \$34.1 million. (*Id.*) Also, the category Other Provisions and Accruals, at \$59.7 million, likely contains a large portion of short-term obligations that would not be included in Roxane's debt-to-equity ratio calculations. (*Id.*)

BIC and BIPI dispute any implication that the 2002 dividend payment was inappropriate or motivated by the Government's 2000 subpoena. No evidence supports this implication; rather it is contradicted by the record evidence, which demonstrates that the amount and timing of the payment were based on legitimate business circumstances and reasons. (*See* BIC and BIPI's Reply to SOF ¶ 36)

BIC and BIPI also dispute that Roxane's 2002 dividend to BIC was inconsistent with Boehringer Ingelheim guidelines. The Government misinterprets the Boehringer Ingelheim guideline and uses the same incorrect debt-to-equity ratio computation described above. The Boehringer Ingelheim guideline applied to the U.S. subsidiaries on a consolidated basis, rather than to the individual debt-to-equity ratios of each subsidiary. (Tab 129, Pomer Declaration at ¶¶ 13-14)

Therefore, a dividend was considered within guideline when the combined debt-to-equity ratio of the U.S. subsidiaries was less than 1.5 to 1. (*Id.*) In addition, for purposes of the dividend guideline, BIC and its subsidiaries calculate their debt to equity ratios based upon the Proposed Treasury Regulations Section 1.163(j)-3, which provides the IRS' definitions and computation guidelines for determining debt-to-equity ratio. (*Id.* at ¶ 15) Under those guidelines, short-term liabilities are excluded from the calculation. (*Id.*) As described above, Roxane's balance sheet as of December 2002 had a significant amount of short-term liabilities that would have been excluded for purposes of determining whether the consolidated ratio was within guideline.

Finally, BIC and BIPI dispute the Government's comparisons of Roxane's debt to equity ratio to those of its competitors as they are based on a flawed, unreliable and therefore irrelevant "analysis" done by the auditor for the Department of Justice, Mr. Ormond. The Government's calculation of Roxane's ratio as it compares to that of several of its competitors is flawed for several reasons: (1) the Government has not demonstrated and provides no basis to conclude that the six entities used in their comparison are comparable to Roxane for these purposes, and, in fact, the data suggests otherwise; (2) the Government has not shown that the financial data used in the calculations is consistent or comparable across either source or time; and (3) the Government's calculations include a variety of confounding factors, such as including short term liabilities and idiosyncratic events. (Tab 130, Steffen Decl. at ¶¶ 4-9) The significant flaws in Mr. Ormond's analysis makes it a wholly unreliable basis upon which to reach any conclusion regarding how Roxane's debt-to-equity ratio compared to its competitors and does not create a genuine issue of fact regarding the adequacy of Roxane's capital. (*Id.* at ¶ 4)

40. Roxane also held substantial assets in its own name, such as its manufacturing plant and equipment, inventories, and the rights, title and interest in its line of products. (Tab 44, BOEH02541150-69 at 11-12 (Commentary 1997 Actual); Tab 49, BOEH00147729-58 at 26-27

(2002 Year-End Financial Commentary); Tab 53, BOEH01046045-6092 (Elan Asset Purchase Agreement))

United States' Response: The United States does not dispute that Roxane has held certain assets in its own name, including those identified in this paragraph.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

III. The Interactions And Relationships Between Roxane, BIPI And BIC Were Appropriate And Typical Of Normal Parent, Subsidiary And Affiliate Relationships.

(a) Inter-company Transactions Were Conducted on Arms-length Terms

41. Starting in 1993, BIPI contracted with Roxane to manufacture certain products, including Atrovent UDV. (Tab 15, McIntyre Dep. 80-81)

United States' Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

42. A 1993 written Contract Manufacturing Agreement provided the terms under which Roxane manufactured products for BIPI. (*Id.* 81, 203-204; Tab 54, McIntyre Ex. 29, BOEH04689322-32 (1993 Contract Manufacturing Agreement) (1993 Contract)) The contract had a ten year renewable term. (Tab 15, McIntyre Dep. 81-82; Tab 54, McIntyre Ex. 29, BOEH04689322-32 at 23 (1993 Contract))

United States' Response: The United States does not dispute that Roxane and BIPI entered into a 1993 contract pursuant to which Roxane manufactured and sold Alupent and Atrovent Solution to BIPI. (Tab 54 at BOEH04689331) Further answering, Roxane manufactured and sold other

products to BIPI which were *not* covered by the 1993 contract including, for example, Mobic. (BIC/BIPI Fauci Exhibit 6 (10/19/2004 Tetzner Dep.) at 144:15 - 145:4)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Undisputed that Roxane manufactured Mobic, which was launched by BIPI in 1996, and thus Mobic was not specifically listed in the original 1993 contract. (Tab 125, Boehringer Ingelheim’s Milestones in Research and Development, <http://boehringerengelheim.com/corporate/research/milestones.asp>) However, this alleged fact is not material to BIC and BIPI’s motion or the Government’s claims against BIC and BIPI because it does not involve a drug at issue in this case.

43. In 2005, after the split of Roxane’s marketing/sales and manufacturing businesses, BIRI and BIPI entered into a new written manufacturing contract. (Tab 15, McIntyre Dep. 204- 205; Tab 55, McIntyre Ex. 30, BOEH04689307-21 (2005 BIRI/BIPI Contract Manufacturing Agreement) (2005 BIRI/BIPI Contract)) At the same time, BIRI and Roxane entered into a written contract manufacturing agreement containing the same terms. (Tab 15, McIntyre Dep. 207-208; Tab 56, McIntyre Ex. 31, BOEH04689293-306 (2005 BIRI/RLI Contract Manufacturing Agreement) (2005 BIRI/RLI Contract)) The 2005 contracts provided that BIPI and RLI would each pay BIRI its cost plus 10% for manufacturing drugs. (Tab 15, McIntyre Dep. 205, 208; Tab 55, McIntyre Ex. 30, BOEH04689307-21 at 15 (2005 BIRI/BIPI Contract); Tab 56, McIntyre Ex. 31, BOEH04689293-306 at 99 (2005 BIRI/RLI Contract))

United States’ Response: Undisputed. Further answering, Roxane’s 2005 reorganization was at least in part, due to Boehringer Ingelheim’s recognition that it operated in the United States with a “variety of legal entities that [did] not necessarily reflect the nature of [its] businesses” and which “often [did] not convey clearly the performance of [its] businesses.” (BIC/BIPI Fauci Exhibit 44)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted

by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Undisputed that BIC/BIPI Fauci Exhibit 44 contains the quoted language. The Government’s quotations, however, are selective, incomplete, and misleading; the document in its entirety is the best evidence of its content. Specifically the purpose of the 2005 reorganization was to address issues arising from the fact that prior to 2005, Roxane had within one legal entity two separate types of business with two reporting structures, a manufacturing business and a sales and marketing business. (Tab 101, 2/26/09 McIntyre Dep. 30)

44. BIPI was originally charged a set price per product under the 1993 agreement. (Tab 54, McIntyre Ex. 29, BOEH04689322-32 at 26, 32 (1993 Contract)) In 2001, BIPI began being charged on a “cost-plus” basis. Roxane’s costs included ingredient costs, labor and overhead, and then a profit percentage was added to the cost. (Tab 15, McIntyre Dep. 82-86) The profit margin Roxane received on its contract manufacturing services under the cost-plus terms put in place in 2001 was later validated as an arms-length rate by a third-party consultant who performed a study in 2004 of pharmaceutical manufacturing contracts between comparable companies and the profit margins those contracts contained. (*Id.* 87-88, 206-207)

United States’ Response: The term “set price per product” is ambiguous as used in this paragraph. Roxane’s corporate representative testified that he was unable to determine what price was charged to BIPI under the 1993 contract, but that he believed the price included some margin to Roxane. He did not know the size of the margin. (BIC/BIPI Fauci Exhibit 45 (2/25/2009 McIntyre Dep.), at 84:20 - 85:12) The United States also does not dispute that beginning in or around 2001, Roxane sold Alupent and Atrovent Solution to BIPI on a “cost- plus” basis, and that the price to BIPI included a 2.2% markup. (*Id.* at 85:13 - 87:22) The United States further admits that in or around 2004, the 2.2% markup was “validated” by “outside consultants.” (*Id.* at 85:13 - 88:14)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). To the extent the Government’s response is anything other than an unqualified admission,

BIC and BIPI object to the Government's response because it is not clear what material facts, if any, it is disputing.

BIC and BIPI dispute that the term "set price per product" is ambiguous and dispute that Roxane's corporate representative testified that he was unable to determine what price was charged to BIPI under the 1993 contract. Mr. McIntyre testified only that he was unable to determine what the "margin" was that was included in the contract prices and exactly how that pricing was determined for the 1993 manufacturing agreement. (Tab 101, 2/26/09 McIntyre Dep. 81-82, 84-85) The set "price" charged by Roxane to BIPI for each product was specifically set forth in an attachment to the 1993 manufacturing agreement. (Tab 54, McIntyre Ex. 29, 1993 Contract Manufacturing Agreement (1993 Contract) at BOEH04689326, BOEH04689332). Further answering, BIC and BIPI state that the 2.2% mark-up referred to by the Government was applied to "full cost," which included the cost of the active pharmaceutical ingredient (API) and that the 2.2% gave the "same absolute margin or absolute profit as ten percent on cost minus API." (Tab 101, 2/26/09 McIntyre Dep. 85-86) Further, Mr. McIntyre testified that the 2.2%/10% mark-up applied to all products that Roxane manufactured for BIPI, not just Alupent and Atrovent as the Government states. (*Id.* at 88)

45. For a period of time between 1996 and 2001, Roxane licensed a BIPI-developed drug called Viramune, which it marketed and sold as part of its HIV and palliative care specialty line. (*Id.* 156-157) Roxane booked the sales for Viramune and paid BIPI an 11% royalty pursuant to a written licensing agreement. (*Id.* 157, 172-173)

United States' Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted

by opposing parties unless controverted by the statement required to be served by opposing parties.”).

46. Roxane also licensed a product called Mexilitine from BIPI for a period of time, and paid an 11% royalty rate pursuant to a written licensing agreement. (Tab 57, BOEH04689278-92 at 285 (1995 BIPI/Roxane Mexilitine License Agreement))

United States’ Response: Undisputed.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

47. Roxane paid the same 11% royalty for the right to market its generic ipratropium bromide under BIPI’s NDA for Atrovent. (Tab 15, McIntyre Dep. 72-73)

United States’ Response: Undisputed.

BIC & BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

48. The 11% royalty Roxane paid had been previously validated by a third-party consultant as an arms-length amount. (*Id.*)

United States’ Response: The United States does not dispute that the 11% royalty rate Roxane paid to BIPI on certain products was the same as the royalty rate paid by BIPI to a Boehringer Ingelheim affiliate in Germany, and that the royalty rate paid by BIPI to its German affiliate was validated by an outside consultant. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.), at 72:13 - 75:7) The paragraph is otherwise denied, and is not supported by the cited authority.

BIC & BIPI's Reply: The Government does not dispute that the 11% royalty rate that BIPI paid to Boehringer Ingelheim International was validated by a third-party consultant as an arms-length amount, and was the same royalty rate that Roxane paid to BIPI for certain products, and therefore those facts are deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Further, as the Government’s own proffered evidence indicates, third-party consultants also validated the 11% royalty rate that Roxane paid to BIPI as “an arm’s length rate.” (BIC/BIPI Fauci Ex. 45, 2/26/09 McIntyre Dep. 74)

(b) Shared Services Were Appropriately Accounted for Between the Companies

49. Certain BIPI departments provided shared services at various times, including accounting, tax, legal, IT and contract administration. (Tab 15, McIntyre Dep. 38-41, 48-49; Tab 20, Russillo Dep. 273-274). Roxane was charged back and paid for the value of the services it used. (Tab 15, McIntyre Dep. 34, 37, 40, 49; Tab 20, Russillo Dep. 271-274)

United States’ Response: The United States does not dispute that employees at BIPI provided services to other Boehringer Ingelheim entities, including Roxane. For example, Mr. Russillo (who supervised Roxane’s multi-source marketing) testified that Roxane’s “AWP practices” were reviewed by lawyers acting on behalf of Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.), at 259:12 - 260:10, 280:14 - 281:21) Likewise, Bruce Banks, an in-house attorney employed by BIPI, was a member of a “pricing committee” (comprised of BIPI and Roxane sales and marketing personnel) which reviewed BIPI and Roxane’s “pricing strategies.” (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.) at 36:18 - 43:1, 91:23 - 94:17)

The United States does not dispute that Roxane was “charged back” for some of these services (including accounting, tax, legal, and IT) on an “accounting basis.” (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.) at 49:15 - 53:9) There is no evidence that Roxane was actually invoiced for these services, however. (*Id.*) Moreover, as noted *supra* in the United States Responses to Paragraph 7, 8, and 14, several BIPI employees played active roles in the marketing and promotion of Roxane’s drugs, including (among others) Mr. King, Mr. Berkle, and Mr. Ciarelli. There is no evidence that Roxane was “charged back” any portion of these employees’ salaries. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.) at 62:16 - 65:9) Likewise, although Mr. Russillo was paid by Ben Venue Labs, he supervised Roxane’s multi-source marketing and there is no evidence Roxane was charged back for any portion of Mr. Russillo’s salary. (*Id.*)

BIC & BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Undisputed that the witnesses testified as quoted. The Government’s quotations, however, are selective, incomplete, and misleading; the entire deposition transcripts are the best evidence of their respective content. Mr. Russillo testified only that “[a]s a result of the lawsuits, our practices were reviewed by lawyers who did investigations.” (Tab 106, 1/8/09 Russillo Dep. 259) In addition, the “pricing committee” to which the Government refers that Mr. Banks was a member of, was unrelated to the review of “AWP practices” referenced in the Government’s earlier sentence or the approval of AWP; rather, it was an ad-hoc committee whose purpose, in relation to antitrust litigation, was in part to identify proposals for pricing for different classes of trade in a way that would not “run[] afoul of the antitrust statutes.” (BIC/BIPI Fauci Ex. 30, 12/3/04 King Dep. 37, 41-42)

The Government provides no evidence that Roxane was *not* invoiced for services, but regardless, the issue is immaterial, because Roxane did pay for those services, a fact which the Government does not dispute. Moreover, with respect to the Government’s contention that there is no evidence that Roxane was charged back for portions of employees’ salaries, Professor Macey testified that in those situations where employees serve dual roles at two companies, the “overwhelming business practice in the United States is to have people receive a single paycheck.” (BIC/BIPI SOF at ¶ 93) Thus, Professor Macey was “not aware of very many, if any, situations where a company would, while having somebody wear two hats go to the sort of, kind of extreme

bureaucratic step . . . [to] pay them two different paychecks . . . it's just inefficient to be paid by both and we don't observe that in the way business is conducted.” (Tab 99, 5/20/09 Macey Dep. 270-71) Further, Professor Macey pointed out that in this case “BIPI, RLI, Ben Venue, and BIC, actually had different pension plans such that it would have been very difficult to take an employee . . . and say, well, you're going to be 80 percent allocated to Roxane and 20 percent allocated to Ben Venue and you'll have – 20 percent of your pension will be here. It would create a truly human resources administrative nightmare.” (*Id.* at 269-70)

50. At the beginning of each year, each department providing shared services would develop an operating budget and present it for approval to each subsidiary. Based on historical averages, an estimate would be made for how much work (*e.g.*, how many hours for legal services) each entity was predicted to use. Each legal entity was charged at a rate that made sense for that service (*e.g.*, hours for legal work). The estimated work and actual work used by each entity was tracked throughout the year so that by the end of the year, the actual charges for each subsidiary could be reconciled. (Tab 15, McIntyre Dep. 51-52)

United States' Response: Undisputed, except there is no evidence Roxane was charged back for any portion of the salaries of the various BIPI or Ben Venue Labs employees who marketed or promoted Roxane's products. *See supra* United States Response to Paragraph 49.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

Roxane hereby incorporates its reply to the United States' Response to Paragraph 49. With respect to the Government's contention that there is no evidence that Roxane was charged back for portions of employees salaries, Professor Macey testified that in those situations where employees serve dual roles at two companies, the “overwhelming business practice in the United States is to have people receive a single paycheck.” (BIC/BIPi SOF at ¶ 93) Thus, Professor Macey was “not

aware of very many, if any, situations where a company would, while having somebody wear two hats go to the sort of, kind of extreme bureaucratic step . . . [to] pay them two different paychecks. . . it's just inefficient to be paid by both and we don't observe that in the way business is conducted." (Tab 99, 5/20/09 Macey Dep. 270-71) Further, Professor Macey pointed out that in this case "BIPI, RLI, Ben Venue, and BIC actually had different pension plans such that it would have been very difficult to take an employee . . . and say, well, you're going to be 80 percent allocated to Roxane and 20 percent allocated to Ben Venue and you'll have – 20 percent of your pension will be here. It would create a truly human resources administrative nightmare." (*Id.* at 269-70)

51. In addition to shared services, a business unit concept was put in place to coordinate high level strategic oversight of BIPI and Roxane's common business areas for a period of time before Roxane divested its few brand products. Sheldon Berkle, a BIPI employee and Roxane board member, was designated as Vice-President of the Business Unit. (Tab 1, 1/27/05 Berkle Dep. 63-64; Tab 2, 10/31/08 Berkle Dep. 186-87) In this role, Mr. Berkle provided only strategic oversight, and was not involved in the day-to-day operations of Roxane. (*Id.*)

United States' Response: The United States does not dispute that in or around 1994, Boehringer Ingelheim created a business unit including Roxane and BIPI (and later Ben Venue Labs), or that Mr. Berkle was in charge of the Business Unit. (*See supra* the United States' Response to Paragraph 7) The United States disputes, however, that the Business Unit only coordinated "high level strategic oversight" of BIPI and Roxane, and that Mr. Berkle "was not involved in the day-to-day operations of Roxane." In fact, Mr. Berkle (as well as other BIPI employees) was actively involved in Roxane's marketing efforts, including approving marketing plans and proposed AWP's for the Subject Drugs.

Further answering, Mr. Berkle was responsible for directing the efforts of senior personnel in the BIPI and Roxane marketing departments, such as Ed Tupa (then Roxane's Vice President of Sales and Marketing) and Fred Duy (then Roxane's Director of Business Development). (BIC/BIPI Fauci Exhibit 14; BIC/BIPI Fauci Exhibit 19 (11/10/2005 Tupa Dep.), at 52:6 - 52:20; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.), at 53:2 - 54:16) In or around May 1996, Roxane implemented "plans for a restructured business unit including the Marketing, Sales and Business Development Departments" at Roxane and BIPI. (BIC/BIPI Fauci Exhibit 17) Specific changes included that "certain former Roxane and BIPI functions" became "a part of the (BU) Business Unit having responsibilities for activities at both Roxane and BIPI." (*Id.*) These functions included "Forecasting, Market Research, Technical Support, Project Management, Managed Care, Sales Support Business Development and Business Intelligence" as well as "the BU Sales Training, BU Trade Relations, the BU Contracts functions." (*Id.*) Additional changes to the Business Unit's management were announced in an October 1998 Employee Bulletin, including that Jim King began to supervise the BIPI/Roxane branded sales force, and BIPI and Roxane contracting were combined

into a “single organization.” (BIC/BIPI Fauci Exhibit 18) In addition, Christine Ferrara (a BIPI employee) began to “manage a unified pricing process for the Business Unit.” (*Id.*; BIC/BIPI Fauci Exhibit 15 (10/31/2009 Berkle Dep.) at 254:22 - 255:2) In that capacity, Ms. Ferrara reported to Gregg Ciarelli (also a BIPI employee). (BIC/BIPI Fauci Exhibit 18; BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.) at 9:17 - 10:11, 13:14 - 14:7, 50:6 - 50:13) These management changes were announced publicly in a January 1999 “news release.” (BIC/BIPI Fauci Exhibit 77) Moreover, a 1999 Roxane organizational chart confirms that several BIPI employees (including Mr. Berkle, Mr. King, Mr. Ciarelli, Mr. Leonetti and others) had responsibilities for marketing and/or promoting Roxane’s drugs. (BIC/BIPI Fauci Exhibit 50) The organizational changes were also described at an October 1998 meeting of the BIC Board of Directors. (BIC/BIPI Fauci Exhibit 16 at BICJURIS0236). Minutes from that states that “sales and marketing for branded generics will report to BIPI counterparts.” (*Id.*)

Consistent with the management structure described in the Business Unit’s organizational charts, news releases and employee bulletins, Roxane and BIPI shared a common “Pricing Policy and Procedure” for BIPI products and Roxane branded generic products (including Subject Drugs Roxicodone, Oramorph SR, and Roxanol). (BIC/BIPI Fauci Exhibit 78; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.) at 214:22 - 215:19) Pursuant to the Pricing Policy and Procedure, recommended prices for Roxane’s branded generic products (including proposed WACs and AWP) required approval first by a pricing committee, comprised jointly of Roxane and BIPI personnel, and then by the “Executive Vice President, Ethical Pharmaceuticals” (Mr. Berkle) and the “President and CEO, Boehringer Ingelheim Corporation” (Mr. Gerstenberg). (BIC/BIPI Fauci Exhibit 78; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.) at 219:20 - 222:15, 343:15 - 344:22) The August 2000 launch of Roxane’s 15 and 30 mg Roxicodone tablets (NDCs 00054-4568025 and 00054-4665025) demonstrates how this procedure operated in practice, and reveals the extent of BIPI’s involvement in setting inflated AWP for Roxane’s products.

On August 12, 2000, Mr. Duy emailed the launch plan and “pricing proposal” for the 15 and 30 mg Roxicodone tablets to Mr. Berkle and several other BIPI employees. (BIC/BIPI Fauci Exhibit 80; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.) at 169:12 - 177:5) This was consistent with Mr. Duy’s general practice. (BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.) at 54:9 - 54:16) The launch plan recommended setting AWP twice as high as WACs in order to create “favorable retail reimbursement” and ensure that providers stocked the products. (BIC/BIPI Fauci Exhibit 80 at Shaffer 001480, 001486, 001516; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.) at 181:9 - 183:15) No fewer than five BIPI employees were involved in the decision to approve the Roxicodone pricing and launch plan. For example, on or about August 14, Ms. Ferrara (a BIPI employee who managed the Business Unit’s pricing process) questioned the calculation of “the average spread to [p]harmacy,” causing Mr. Duy to adjust the proposal accordingly. (BIC/BIPI Fauci Exhibit 81) On or about August 15, Mr. Berkle asked Ms. Ferrara whether it was possible to “speed up” the price review process (BIC/BIPI Fauci Exhibit 82), and in the following days several BIPI employees reviewed and endorsed the launch plan including, Mr. Ciarelli, Mr. Leonetti, Mr. King and David Laros (BIC/BIPI Fauci Exhibit 83; BIC/BIPI Fauci Exhibit 84; BIC/BIPI Fauci Exhibit 85; BIC/BIPI Fauci Exhibit 20 (12/16/2008 Duy Dep.) at 196:1 - 198:6, 202:18 - 203:19; BIC/BIPI Fauci Exhibit 107) Mr. Leonetti commented on the “very favorable pharmacy spread” and asked if First Data Bank would publish these prices. Mr. Leonetti concluded, “I guess it really does not matter if it’s published as long as the pharmacist knows the true WAC.” (BIC/BIPI Fauci Exhibit 83 at BOEH00236099)

On or about August 22, 2000, the pricing committee (including BIPI employees Ferrara, Ciarelli, Leonetti and King) formally recommended that Mr. Berkle and Mr. Gerstenberg approve the pricing for the Roxicodone products. (BIC/BIPI Fauci Exhibit 86) The Pricing Committee described the proposed AWP as “compatible with the reimbursement model that drives retailer profit.” (*Id.*) Based in part on the committee’s recommendation, Mr. Berkle and Mr. Gerstenberg approved the launch plan and proposed pricing for the Roxicodone products. (BIC/BIPI Fauci Exhibit 87; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.) at 231:19 - 236:9, 254:14 - 256:15, 265:9 - 266:4, 337:8 - 339:16, 341:19 - 344:22) As noted *supra*, Mr. Berkle was employed by BIPI, not Roxane (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.), at 53:1 - 53:18), and the Pricing Policy and Procedure specifically provided that the prices be approved by the *President and CEO, Boehringer Ingelheim Corporation.*” (BIC/BIPI Fauci Exhibit 78) (emphasis supplied), indicating that Mr. Gerstenberg approved the prices in his role as President and CEO of BIC.

A similar approval process was followed for pricing on several other Roxane drugs. (*See, e.g.,* BIC/BIPI Fauci Exhibit 88; BIC/BIPI Fauci Exhibit 89; BIC/BIPI Fauci Exhibit 90; BIC/BIPI Fauci Exhibit 91)

BIC and BIPI’s Reply: The Government does not dispute BIC and BIPI’s statement of fact that for a period of time a “Business Unit” concept was put in place to coordinate BIPI and Roxane’s common business areas and that Sheldon Berkle was Vice President of this Business Unit, thus these facts are deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). While the Government disputes that the Business Unit only coordinated “high level strategic oversight” of BIPI and Roxane, and that Mr. Berkle “was not involved in the day-to-day operations of Roxane” it provides no basis for or record evidence supporting its dispute and therefore BIC and BIPI object to the Government’s purported dispute and these facts should be deemed admitted. The evidence supports BIC and BIPI’s fact that Mr. Berkle only had high-level, strategic oversight over Roxane’s business. (Tab 90, 10/31/08 Berkle Dep. 38; Tab 89, 1/27/05 Berkle Dep. 23-24; BIC and BIPI’s Reply to SOF ¶ 7, *supra*) BIC and BIPI dispute the Government’s statement that “Mr. Berkle (as well as other BIPI employees) was actively involved in Roxane’s marketing efforts, including approving marketing plans and proposed AWP for the Subject Drugs” as the

Government provides no basis for this alleged fact and it is not supported by proper citations to the record. *See O'Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding “purported statements of ‘fact’ not properly supported by citations to the record” in summary judgment pleadings as required by Local Rule 56.1). Regardless, even if Mr. Berkle was materially involved in Roxane’s marketing efforts, it is immaterial to BIC and BIPI’s motion for summary judgment as Mr. Berkle was a Roxane director and was given a specific management oversight role for Roxane as Head of the Business Unit, and therefore his actions were taken on behalf of Roxane pursuant to those positions. (BIC/BIPI SOF at ¶ 91) The Government’s additional facts do not create a disputed issue of fact material to BIC and BIPI’s motion.

BIC and BIPI do not dispute that Mr. Tupa and Mr. Duy functionally reported to Mr. Berkle in his role as Head of the Business Unit Ethical Pharmaceuticals wherein there was a “dotted line” reporting relationship to Mr. Berkle, who would provide “functional advice” to Roxane. As the Government’s own evidence indicates, however, Mr. Tupa and Mr. Duy continued to have a direct reporting relationship to the President and COO of Roxane. (BIC/BIPI Fauci Ex. 14, BIPI/BIC Job Description re Vice President at RLI-TX 62839; BIC/BIPI Fauci Ex. 19, 11/10/05 Tupa Dep. 52; BIC/BIPI Fauci Ex. 20, 12/16/08 Duy Dep. 53-54) Moreover, when Mr. Russillo took over Mr. Tupa’s role with regard to multisource products, he testified that he did not report to Mr. Berkle, but only to Mr. Gerstenberg, who was the President and COO of Roxane at the time. (Tab 106, 1/8/09 Russillo Dep. 29; BIC/BIPI SOF at ¶ 30) In addition, as discussed above, the evidence establishes that Mr. Tupa continued to lead Roxane’s Marketing and Sales department and handle the day-to-day operational marketing and sales activities. (Tab 90, 10/31/08 Berkle Dep. 38 (Berkle only had “strategic oversight of Roxane, [] Roxane had its own management team and it was responsible for the annual budgets, marketing plans, day-to-day operations.”), 50-51, 125; Tab 89,

1/27/05 Berkle Dep. 23-24; Tab 61, 5/3/96 Reorganization Announcement (“The Roxane Marketing & Sales Department will be led by Mr. Edward Tupa, who currently has this responsibility.”)) Indeed, Mr. Berkle explained that the goal of the business unit was to “do away with wasted effort,” to avoid duplication,” and “to amalgamate services that were common to the various companies,” but that “Roxane and BIPI were always separate entities, they were always separate management within each entity and the day-to-day business for each of those entities was done within that entity.” (Tab 90, 10/31/08 Berkle Dep. 186-87) This type of functional coordination between affiliates to achieve efficiencies is common practice. (Tab 98, 5/19/09 Macey Dep. 72-77) Further, although Roxane and BIPI were part of the same business unit for internal functional purposes, the record is clear that Roxane and BIPI remained two separate legal entities and that their separate corporate identifies were respected; Roxane and BIPI maintained separate Board of directors, offices, employees, financial statements and accounting records, and marketing and sales departments. (Tab 63, 10/23/98 Reorganization Memo at 2 (“We will continue to maintain separate legal entities for BIPI, RLI and BVL”)); BIC/BIPI SOF at ¶¶ 4-9, 15, 21-40, 52) Thus, BIC and BIPI dispute that the Government’s additional facts are material to their motion for summary judgment or the Government’s direct liability and veil-piercing claims as they do not demonstrate that BIC or BIPI were involved in setting or reporting AWP’s for any Subject Drugs or that there was a lack of corporate separateness between BIPI and Roxane or that BIPI pervasively controlled Roxane.

BIC and BIPI do not dispute that in or around May 1996, the President and COO of Roxane announced “plans for a restructured business unit including the Marketing, Sales and Business Development Departments” at Roxane and BIPI or that BIC/BIPI Fauci Exhibit 17 contains the statements quoted by the Government. The Government’s quotations, however, are selective and incomplete; the entirety of the document is the best evidence of its content. Importantly, Roxane’s

Sales and Marketing Department, which was responsible for setting and changing AWP, was not consolidated for Business Unit purposes and the functions that were consolidated reported to Ed Tupa, a Roxane employee. As such, BIC and BIPI dispute that these additional facts are material to their motion for summary judgment or the Government's direct liability and veil-piercing claims as they do not demonstrate that BIC or BIPI were involved in setting or reporting AWP for any Subject Drugs or that BIC or BIPI pervasively controlled Roxane.

BIC and BIPI do not dispute that further organizational changes related solely to Roxane's brand and branded generic products were announced in an October 1998 Employee Bulletin or that the Bulletin, BIC/BIPI Fauci Exhibit 18, contains the statements quoted by the Government. The Government's quotations, however, are selective, incomplete and misleading; the entirety of the document is the best evidence of its contents. BIC and BIPI do not dispute that in an effort to leverage the expertise and experience of several BIPI employees for the benefit of Roxane, Mr. King, Mr. Ciarelli and Mr. Leonetti were given additional high-level supervisory positions for Roxane's brand and branded generic products in October 1998. (Tab 90, 10/31/08 Berkle Dep. 191-92) Nor do BIC and BIPI dispute that these new positions were announced in a January 1999 press release or that these individuals were listed on a 1999 Roxane organizational chart. Specifically, Mr. King became Head, BIPI/RLI Branded Sales; Mr. Ciarelli became Head, Contracting, Pricing & Market Controlling; Mr. Leonetti became Head, Managed Care and Trade Relations; and Mr. Fulton became Head, BIPI/RLI Branded Marketing. (BIC/BIPI Fauci Ex. 77, 1/28/99 Boehringer News Release) As Professor Macey testified, it is common for affiliated companies to have common management personnel and for employees to wear multiple hats. (BIC/BIPI SOF at ¶ 90) In addition, it is the undisputed testimony of Mr. Berkle that even though these BIPI employees were added as an additional level of management for Roxane's brand and branded generic products,

Roxane employees continued to be responsible for and handle the day-to-day operational sales and marketing activities for these products. (Tab 90, 10/31/08 Berkle Dep. 59-60, 191-92; BIC/BIPI SOF at ¶ 79) Indeed, the Roxane directors of each of the affected departments remained in place and continued to manage the Roxane employees in those departments. For example, Gary Ellexson remained the Director of RLI Branded and Specialty Marketing, Jerry Hart remained the Director of RLI Sales, and Mr. Powers continued to lead Roxane's contract department. (Tab 63, 10/23/98 Reorganization Memo at 3-4; BIC/BIPI Fauci Ex. 50, 1999 Roxane Org. Chart) Moreover, to the extent these employees were involved in marketing and sales for Roxane's branded generics, they were acting pursuant to the positions and responsibilities they were given on behalf of Roxane. (BIC/BIPI SOF at ¶ 93)

Further, with regard to the effort to combine contracting into a "single organization," John Powers, a Roxane employee, was assigned to "lead the day-to-day management of this operation." (Tab 63, 10/23/98 Reorganization Memo at 4) In addition, Mr. Berkle explained that "[t]his happened really from the administrative perspective . . . the actual establishment of pricing or contracting was done by individuals within the Roxane business entity, but the processing of the administration . . . [was] done by a central unit" (Tab 90, 10/31/08 Berkle Dep. 60) BIC and BIPI dispute that "Christine Ferrara (a BIPI employee) began to 'manage a unified pricing process for the Business Unit.'" There is no evidence that this process was ever developed or implemented. Indeed, as discussed in detail below, the only evidence the Government points to regarding the establishment of a unified pricing process is a May 2001 draft policy that was circulated for comment. Thus, BIC and BIPI dispute that the Government's alleged facts relating to the October 1998 reorganization for brand and branded generic products are material to their motion for summary judgment or the Government's direct liability or veil-piercing claims as they do not

demonstrate that BIC or BIPI were involved in setting or reporting AWP for any Subject Drugs and do not demonstrate lack of corporate separateness between BIPI and Roxane or that BIC or BIPI pervasively controlled Roxane.

As just stated, BIC and BIPI dispute that “Roxane and BIPI shared a common ‘Pricing Policy and Procedure’ for BIPI products and Roxane branded generic products (including Subject Drugs Roxicodone, Oramorph SR, and Roxanol),” that “[p]ursuant to the Pricing Policy and Procedure, recommended prices for Roxane’s branded generic products (including proposed WACs and AWP) required approval first by a pricing committee, comprised jointly of Roxane and BIPI personnel, and then by the ‘Executive Vice President, Ethical Pharmaceuticals’ (Mr. Berkle) and the ‘President and CEO, Boehringer Ingelheim Corporation’ (Mr. Gerstenberg)” as these alleged facts are not supported by the Government’s proffered evidence, BIC/BIPI Fauci Exhibit 78 and Mr. Berkle’s testimony. The Government’s reliance on BIC/BIPI Fauci Exhibit 78, the “Pricing Policy and Procedure” document is specious for several reasons. First, the “Pricing Policy and Procedure” document was a non-final, *draft* policy circulated to several employees for comment. (BIC/BIPI Fauci Ex. 78, 5/3/01 Email attaching Draft Pricing Policy and Procedure at RLI-AWP-00337203 (“All, Please review the attached ‘Draft’ Pricing Policy and Procedure and provide me any changes you deem appropriate.”)) The Government points to no credible evidence this *draft* policy was ever implemented or that Roxane set any AWP for a Subject Drug pursuant to these proposed practices. Indeed, Mr. Berkle testified that he only recalled the policy being implemented with respect to BIPI products, not Roxane’s brand and branded generic products. (Tab 90, 10/31/08 Berkle Dep. 225-26) The only attempt the Government makes to “demonstrate how this procedure operated in practice” is in relation to the launch AWP of Roxicodone 15mg and 30mg tablets, which could not possibly have been set or approved pursuant to this policy since the launch occurred in August/September 2000

and the draft policy was not circulated until May of the following year. (US Roxane SOF at ¶ 98; BIC/BIPI Fauci Ex. 78, 5/3/01 Email attaching Draft Pricing Policy and Procedure) Second, the Government admits the draft “Pricing Policy and Procedure” document only relates to Roxane’s branded and branded generic products, namely Roxicodone, Oramorph SR, and Roxanol. Since Roxane divested these three products in September 2001 and the draft document is dated May 2001, the policy would have only been in place for a few months, if it was implemented at all. (Tab 90, 10/31/08 Berkle Dep. 215-16, 225-26; BIC/BIPI SOF at ¶ 81) Thus, BIC and BIPI dispute that this fact or the draft pricing policy are material to BIC and BIPI’s motion for summary judgment or the Government’s direct liability claim against them because it does not establish that BIC or BIPI set, approved or reported AWP’s for any Subject Drugs that the Government asserts are false. BIC and BIPI also dispute that this fact or the draft pricing policy are material to their motion or the Government’s veil-piercing claim against them because they do not demonstrate a lack of independence between Roxane and BIPI and BIC or that BIPI and BIC pervasively controlled Roxane.

For the reasons just stated, BIC and BIPI dispute that “[t]he August 2000 launch of Roxane’s 15 and 30 mg Roxicodone tablets (NDCs 00054-4568025 [sic] and 00054-4665025 [sic]) demonstrates how this procedure operated in practice, and reveals the extent of BIPI’s involvement in setting inflated AWP’s for Roxane’s products.” The May 2001 “Pricing Policy and Procedure” document could not have informed the August/September 2000 launch of certain Roxicodone products because the draft policy was written nine months *after* the launch. (BIC/BIPI Fauci Ex. 78, 5/3/01 Email attaching Draft Pricing Policy and Procedure) BIC and BIPI do not dispute that Mr. Duy e-mailed the launch plan and pricing proposal for the 15 and 30mg Roxicodone tablets to Mr. Berkle and several BIPI employees on August 12, 2000. BIC and BIPI dispute that it was

Mr. Duy's "general practice" to obtain approval from Mr. Berkle, as Mr. Duy merely testified that he obtained Mr. Berkle's approval for "significant" changes that would require input from Mr. Berkle in his functional role as Vice President of the Ethical Pharmaceuticals Business Unit. (BIC/BIPI Fauci Ex. 20, 12/16/08 Duy Dep. 53-54) Mr. Duy testified:

Although – if we were coming up – if I was coming up with a business plan that had to do with a human pharmaceutical drug, even though I reported to the president of Roxane and – and would talk to him, I would also talk to Shelly about how this fits into his sphere of the business, and he would have to approve of what we were doing.

(*Id.* at 54) This is consistent with Roxane's practice of ensuring its practices were consistent with BIC's overall strategy for its subsidiaries and to benefit from BIPI's experience marketing branded drugs, while still maintaining day-to-day operations within Roxane. (*Id.*; BIC/BIPI SOF at ¶¶ 75, 78-79) Accordingly, it was Roxane employees and consultants that wrote and developed the Roxicodone launch plan and AWP and WAC proposal, not BIPI or BIC employees. (Tab 126, Duy Ex. 32, 8/1/00 Email re Roxane Marketing Resources; BIC/BIPI Fauci Ex. 20, 12/16/08 Duy Dep. 173-74; BIC/BIPI Fauci Ex. 15, 10/31/08 Berkle Dep. 234; BIC/BIPI Fauci Ex. 80, 8/12/00 Email attaching Roxicodone 15/30mg Launch Plan; BIC/BIPI SOF at ¶ 79)

BIC and BIPI do not dispute that a handful of BIPI employees received and commented on the draft Roxicodone launch plan and pricing proposal circulated by Mr. Duy or that Mr. Berkle and Mr. Gerstenberg approved the launch prices for Roxicodone 15mg and 30mg tablets. Importantly, the launch prices and plan were approved as drafted and proposed by Roxane's marketing group and employees. (*See* BIC/BIPI Fauci Ex. 86, 8/22/00 Boehringer Memo re Recommended Pricing for Roxicodone IR; BIC/BIPI Fauci Ex. 87, 8/24/00 Email re Roxicodone WAC AWP proposal; BIC/BIPI Fauci Ex. 80, 8/12/00 Email attaching Roxicodone 15/30mg Launch Plan at SHAFFER 001516) In addition, the BIPI personnel that commented on the Roxicodone proposal held high-level supervisory roles with respect to Roxane's brand and branded generic products or had positions

in a consolidated or shared service department, like contract pricing and administration. (BIC/BIPi Fauci Ex. 18, 10/23/98 Employee Bulletin re Organizational Changes at 3-4 (King, Leonetti, and Ciarelli given or held supervisory positions); Tab 91, 6/26/02 Ciarelli Dep. 16-17 (Ciarelli and Ferrara, who worked for Ciarelli, were responsible for shared contracts pricing administration)) Thus, to the extent they approved or commented on the launch prices for Roxicodone, they were acting on behalf of Roxane, not BIPi.

BIC and BIPi dispute the Government's alleged fact that that "Mr. Gerstenberg approved the [Roxicodone] prices in his role as President and CEO of BIC." The Government's support for this statement is that the "Pricing Policy and Procedure" document referenced above indicated that certain prices be approved by "President and CEO, Boehringer Ingelheim Corporation." (BIC/BIPi Fauci Ex. 78, 5/3/01 Email attaching draft Pricing Policy and Procedure) But the "Pricing Policy and Procedure" is dated nine months *after* Mr. Gerstenberg purportedly "approved" the Roxicodone pricing. The Government has no credible evidence Mr. Gerstenberg approved the pricing in his role as President and CEO of BIC rather than in his role as President and COO of Roxane. (BIC/BIPi SOF at ¶ 30) Rather, Mr. Russillo's testimony establishes that to the extent Mr. Gerstenberg was involved in Roxane AWP or pricing decisions he "would have been acting as the President of Roxane." (*See* BIC and BIPi's Reply to SOF ¶¶ 61-62, 71)

Because the Government's alleged facts relating to the launch of Roxicodone 15 and 30mg tablets do not demonstrate that BIPi or BIC employees set or reported the AWP for these products and, to the extent they were involved in providing input or approving the AWP, they were acting on behalf Roxane, BIC and BIPi dispute that these facts are material to their motion for summary judgment or the Government's direct liability claims against them. In addition, BIC and BIPi dispute that the Government's alleged facts relating to the Roxicodone 15 and 30mg tablets are

material to their motion for summary judgment or the Government's veil-piercing claims against them as they do not demonstrate a lack of independence between Roxane and BIC or BIPI or that BIC or BIPI pervasively controlled Roxane; rather, they demonstrate only that for the launch of one drug, Roxane sought to benefit from BIPI's experience marketing branded drugs, a common practice among affiliated companies.

The Government's alleged fact that "[a] similar approval process was followed for pricing on several other Roxane drugs" is not material to the Government's claims because the Government's proffered evidence only relates to drugs not at issue in this action. (*See* BIC/BIPI Fauci Ex. 88, 8/23/99 Email re Price Increase Documents (relating to the brand/branded generic drug Marinol, which is not at issue); BIC/BIPI Fauci Ex. 89, 8/18/99 Email re Documents to be signed (relating to the brand/branded generic drug Marinol, which is not at issue); BIC/BIPI Fauci Ex. 90, 11/8/99 Memo re Recommended Pricing: Duraclon (relating to the brand/branded generic drug Duraclon, which is not at issue); BIC/BIPI Fauci Ex. 91, 2001 Memo re Recommended BIPI Price Increases for Q1 2002) (relating to the drugs Cafit and Torecan, which are not at issue))

Further, while BIC and BIPI do not dispute that the documents related to the launch of Roxicodone 15 and 30mg tablets contain the quotes the Government references, the quotes are immaterial to their motion for summary judgment. In addition, the Government's selected quotes of "favorable retail reimbursement," calculation of "the average spread to [p]harmacy," "very favorable pharmacy spread," and "compatible with the reimbursement model that drives retailer profit" are selective, incomplete and misleading; the documents in their entirety are the best evidence of their content. The entirety of the document and witness testimony establish that the prices for Roxicodone 15 and 30mg were set "reasonably comparable" to competitive prices for 5mg tablets and at a level such that retailer profit would be "similar" to 5mg generic oxycodone products, with

the goal that there would be no incentive for the pharmacist to substitute three or six 5mg generic tablets for prescriptions of Roxicodone 15mg or 30mg. In other words, Roxane set the prices so the new strengths would not be disadvantaged at the pharmacy level and would remain competitive. (BIC/BIPI Fauci Ex. 80, 8/12/00 Email attaching Roxicodone 15/30mg Launch Plan at SHAFFER 001516; Tab 107, 5/21/08 Shaffer Dep. 218-19; Tab 94, 12/16/08 Duy Dep. 181-83, 185) In addition, Roxane states that its core sales message for Roxicodone was directed to physicians, not pharmacies, and focused on the therapeutic advantages of the unique 15mg and 30mg strengths. (BIC/BIPI Fauci Ex. 80, 8/12/00 Email attaching Roxicodone 15/30mg Launch Plan at SHAFFER 001492-1507; Tab 108, 8/5/08 Shaffer Dep. 369-72; Tab 127, Shaffer Ex. 27, Roxicodone 15/30mg Launch Plan Overview Presentation at 8-18) Roxane further states that the 15mg and 30mg Roxicodone products were only actively marketed by Roxane for the short time period between late September 2000 and December 2000, when the Roxane palliative care sales force was disbanded, and that in September 2001 the products were divested to Elan Pharma International Ltd. (Tab 108, 8/5/08 Shaffer Dep. 367-68; Roxane SOF at ¶ 253) Finally, the Government's selective quotation of Mr. Leonetti's remark that "I guess it really does not matter if it's published as long as the pharmacist knows the true WAC" is misleading. As the few sentences before the Government's quoted sentence reveal, Mr. Leonetti was referring to First DataBank's practice of calculating AWP for brand drugs based on a 20-25% markup from WAC:

Speaking of favorable spread, can we really get a published 50% AWP-WAC spread. I thought First Data or other pricing reference services calculates the spread? I guess it really does not matter if it's published as long as the pharmacist knows the true WAC.

(BIC/BIPI Fauci Ex. 83, 8/18/00 Email re Roxicodone 15/30mg Launch Plan at BOEH00236099)

IV. Roxane Controlled Its Day-to-Day Business Operations, Including The Pricing And Marketing Of Its Products.

(a) Marketing and Pricing of Multi-source Generic Products

52. Roxane had its own marketing and sales departments which were responsible for promoting its products. (Tab 2, 10/31/08 Berkle Dep. 324; Tab 22, 8/5/08 Shaffer Dep. 380; Tab 9, 11/18/05 Feldman Dep. 76; Tab 1, 1/27/05 Berkle Dep. 25; Tab 58, D0530608 (2003 Multisource Sales & Marketing Organizational Chart); Tab 59, RLI-ORG00000080 (1996 Budget Organizational Chart); Tab 60, RLI-ORG00000017 (Jan. 1998 Organizational Chart))

United States' Response: Disputed. As discussed *supra* in the United States Responses to Paragraphs 7, 8, 14 and 51, BIPI and BIC employees played important roles in marketing Roxane's products, including by approving marketing strategies and prices.

BIC and BIPI's Reply: The Government's additional facts do not contradict BIC and BIPI's stated fact that Roxane had its own marketing and sales departments which were responsible for promoting its products and therefore this fact should be deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). BIC and BIPI dispute that "BIPI and BIC employees played important roles in marketing Roxane's products, including by approving marketing strategies and prices." (*See* BIC and BIPI's Reply to SOF ¶¶ 7, 8, 14 and 51)

53. Judy Waterer began as Roxane's Manager for Multisource Program Development in 1996. In this position, Waterer was responsible for Roxane's multi-source marketing activities, including launches, training sales representatives, advertising, and pricing. (Tab 26, 10/24/01 Waterer Dep. 31-34) In the early 2000s, Lesli Paoletti, a member of the marketing department, took over many of these responsibilities from Ms. Waterer. (Tab 18, 7/26/07 Paoletti Dep. 15- 16; Tab 29, 5/9/07 Waterer Dep. 38, 64-65; Tab 29, 5/10/07 Waterer Dep. 282-283)

United States' Response: The United States does not dispute that Ms. Waterer and later Ms. Paoletti were involved in "Roxane's multi-source marketing activities." The United States disputes this paragraph, however, to the extent it implies that Ms. Waterer and Ms. Paoletti were solely responsible for these activities, or that BIC and/or BIPI were not actively involved in the conduct for which the United States is seeking damages.

Ms. Waterer reported first to Ed Tupa and then to Tom Russillo. (BIC/BIPI Fauci Exhibit 11 (10/24/2001 Waterer Dep.) at 34:8 - 36:3, 54:9 - 55:2, 57:8 - 57:18) During Mr. Tupa's tenure as Roxane's Vice President of Marketing, Boehringer Ingelheim personnel were involved in decisions

to approve marketing plans and prices for Roxane's multi-source drugs. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.) at 35:25 - 38:4; BIC/BIPI Fauci Exhibit 19 (11/10/2005 Tupa Dep.) at 52:17 - 53:10) For example, several BIPI employees met with Roxane personnel (including Mr. Tupa) in January 1996 to discuss marketing strategies for ipratropium bromide. (BIC/BIPI Fauci Exhibit 24 at RLI-AWP-00299558) Minutes from this meeting reflect a discussion of "Medicare reimbursement" and agreement that the AWP for ipratropium bromide should be set at 10% below Atrovent's AWP. (*Id.*) The ipratropium bromide launch plan explained that this pricing structure was used to create an attractive spread between WAC and AWP and thereby "entice" accounts to switch from the brand name to the generic product. (BIC/BIPI Fauci Exhibit 21 at ROX-TX 01344) Mr. Tupa testified that BIPI personnel, including Mr. Berkle, were involved in the decision to approve the ipratropium bromide marketing plan. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.) at 36:15 - 37:17)

Mr. Russillo testified that he reported to Mr. Gerstenberg "in his role as president and CEO of BIC." (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 204:1 - 204:7, 206:17 - 207:2, 221:22 - 223:5) Mr. Russillo consulted with BIC and/or BIPI personnel, including members of the pricing committee, on pricing issues that were regarded as "sensitive" or likely to raise "legal" or "government" issues. (BIC/BIPI Fauci Exhibit 92 at BOEH01311860; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 98:1 - 98:16) For example, in or around July 2000, Mr. Russillo was involved in the decision to raise the AWP's on Roxane's furosemide products by up as much as 300%. Mr. Russillo testified that as of at least 1999, he and members of BIC and BIPI's senior management knew the government was scrutinizing AWP's and therefore regarded any decision to raise AWP's as "sensitive" and requiring BIC's approval. (*Id.*, at 98:9 - 99:7, 179:22 - 180:16 ("The mood at Boehringer Ingelheim was the same as mine. It was very sensitive to AWP changes"); BIC/BIPI Fauci Exhibit 58 (11/28/2005 Waterer Dep.) at 48:19 - 51:5)

Nonetheless, Mr. Russillo was prepared to "champion" and "support" the Furosemide AWP increase and take the proposal "up the line." (BIC/BIPI Fauci Exhibit 93; BIC/BIPI Fauci Exhibit 94) On July 7, 2000, Mr. Russillo advised Robert Sykora (a BIPI employee who testified his primary responsibilities were for Roxane) that "[t]o get the approval we need from Connecticut" we "need some 'hard' info" about competitors' AWP's. (BIC/BIPI Fauci Exhibit 95) As noted *supra*, Mr. Russillo testified that at Roxane, "Connecticut" meant Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 36:5 - 36:22)

On July 26, 2000, Mr. Sykora submitted a "sales justification" memorandum and, shortly thereafter, Mr. Russillo received the "official okay to implement the furosemide price changes." (BIC/BIPI Fauci Exhibit 96) Mr. Russillo testified that he endorsed the proposed AWP increase only after learning over the course of "many conversations" that Mr. Gerstenberg supported raising Roxane's AWP's to match competitors. (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 172:18 - 174:3, 192:11 - 194:3 ("Once I had established Werner Gerstenberg's position on this, I would have implemented it"), 222:21 - 223:1)

In addition, other BIPI employees recommended marketing strategies for Roxane's multi-source drugs, including to set inflated AWP's. For example, James Rowenhorst was employed by BIPI in various positions, including as "Manager of Reimbursements." (BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.) at 27:10 - 27:20) Although Mr. Rowenhorst was employed by BIPI, he testified that he "was involved in working with Roxane to ensure that reimbursement channels were

available for the sale of our products if there seemed to be any reimbursement obstacles in the marketplace.” (*Id.* at 71:18 - 72:3, 203:1 - 203:15) In June 2000, Mr. Rowenhorst circulated an email including a Wall Street Journal article entitled “Medicare Plans Major Overhaul, Targets Massive Overpayments.” (BIC/BIPI Fauci Exhibit 97) Although the article specifically noted that “State and federal officials believe that some drug companies are reporting artificially inflated AWP to industry guides that are used for government- reimbursement purposes,” Mr. Rowenhorst recommended that Roxane continue to “focus on a higher AWP and WAC” as a way to keep competitive with Dey Laboratories for sales of several products, including ipratropium bromide. (*Id.*)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). The Government’s additional facts do not controvert BIC and BIPI’s statement of fact and do not create a disputed issue of fact material to BIC and BIPI’s motion for summary judgment.

BIC and BIPI dispute that during Mr. Tupa’s tenure, BIPI employees “were involved in decisions to approve marketing plans and prices for Roxane’s multi-source drugs” as this alleged fact is not supported by the Government’s proffered evidence. First, the Government only cites one instance of alleged involvement by BIPI employees in setting prices for Roxane’s drugs during this time, the unique situation of the launch of ipratropium bromide, where Roxane was launching the generic version of a BIPI brand product. (Tab 89, 1/27/05 Berkle Dep. 72-73 (“[I]n the case of ipratropium which was a unique case because the branded product was marketed by [BIPI] . . . [t]here was a sharing of information to make sure everybody on both sides . . . knew it was occurring in the marketplace. . . .”)) This single instance, especially given the unique circumstances, does not support that BIPI was routinely involved in Roxane’s pricing or marketing decisions. Second, even for ipratropium bromide, the evidence does not establish that BIPI employees were involved in determining the AWP and WAC figures.

BIC and BIPI do not dispute that BIPI and Roxane employees met and discussed the launch of Roxane's ipratropium bromide product at a meeting that appears from BIC/BIPI Fauci Exhibit 24 to have occurred in January 1996, as it would make sense such discussions would occur given that Roxane's ipratropium bromide product was the first generic version of BIPI's Atrovent product. (Tab 110, 10/18/05 Via Dep. 60-61) However, BIC and BIPI dispute any implication there was more than one meeting between BIPI and Roxane employees, or that the meeting participants discussed anything beyond a general ipratropium bromide market overview. (*Id.* at 66; BIC/BIPI Fauci Ex. 24, Ipratropium Bromide UDV Generic Launch Meeting Summary at ROX 04290; Tab 89, 1/27/05 Berkle Dep. 28 (“[T]here was cross fertilization of general information about our experiences with Atrovent.”); Tab 90, 10/31/08 Berkle Dep. 78 (there was no coordination between BIPI and Roxane regarding how ipratropium bromide was marketed except “[i]n the sense that we were sister companies and there was discussions between the two companies relative to the experience that BIPI had in the marketing with Atrovent”)) BIC and BIPI dispute that at this meeting BIPI personnel provided any input in or “agreed to” setting the launch AWP for ipratropium bromide at 10% less than the Atrovent AWP. BIC/BIPI Fauci Exhibit 24 merely reflects that “[i]t should be noted that the AWP for IBUDV will be 10% below Atrovent’s AWP at the time of launch,” implying this had already been determined by Roxane. (BIC/BIPI Fauci Ex. 24, Ipratropium Bromide UDV Generic Launch Meeting Summary at ROX 04291-92) Indeed, the AWP for ipratropium bromide was set at 10% below the brand in accordance with “the traditional parameters of a generic product” and standard practice at Roxane and thus there was little to decide or discuss regarding ipratropium bromide’s AWP, especially with a brand drug company like BIPI. (*See* BIC/BIPI Fauci Ex. 21, T. Via’s 4/17/96 Ipratropium Inhalation Solution Marketing Plan at 5; Roxane SOF at ¶ 99)

BIC and BIPI dispute that “Mr. Tupa testified that BIPI personnel, including Mr. Berkle, were involved in the decision to approve the ipratropium bromide marketing plan” as it is not supported by the Government’s proffered evidence. Mr. Tupa testified only that “the president of the company would be involved, and I – I – I *believe* that Mr. Berkle had been involved as well.” (BIC/BIPI Fauci Ex. 25, 1/31/03 Tupa Dep. 37 (emphasis added)) Mr. Berkle testified that he did not recall approving the marketing plan for ipratropium bromide and that “I would not have had access necessarily to the detailed marketing plan. I was concerned with the overall forecasts and general strategies, but not in the nitty-gritty of the marketing plan. Mr. Wojta [the President of Roxane at the time] really had the responsibility and the authority to approve that.” (Tab 89, 1/27/05 Berkle Dep. 107) Further, the AWP launch figure was only one small piece of the overall marketing plan prepared by Mr. Via, and Mr. Berkle unequivocally testified that “anything to do with the establishment of pricing [for ipratropium bromide] was decided within the Roxane organization, had to be approved by the CEO of the Roxane – or the president of the Roxane organization.” (*Id.* at 72-73; *see also* Tab 90, 10/31/08 Berkle Dep. 77-78 (“I was not involved in the marketing or pricing of Ipratropium Bromide.”))

Thus, BIC and BIPI dispute that the Government’s alleged facts related to the launch of ipratropium bromide are material to their motion for summary judgment or the Government’s direct liability or veil-piercing claims against them as they do not demonstrate that BIC or BIPI were involved in setting or reporting AWP for any Subject Drugs nor do they demonstrate a lack of independence of Roxane from BIC or BIPI or that BIC or BIPI pervasively controlled Roxane. In addition, BIC disputes that the Government’s facts related to the launch of ipratropium bromide are material to its motion for summary judgment or the Government’s claims against it as they relate solely to BIPI. BIC and BIPI dispute that the “spread” between the WAC and AWP for ipratropium

bromide is material to their motion for summary judgment and states that Roxane's purpose in creating an AWP/WAC spread for ipratropium bromide was to "encourag[e] accounts to convert from the brand name to the generic product as quickly as possible" (BIC/BIPI Fauci Ex. 21, T. Via's 4/17/96 Ipratropium Inhalation Solution UDV Marketing Plan at 5), a goal that CMS itself just recently stated justified AWP to acquisition costs spreads as high as 73%. (Tab 119, January 2008 OIG Report at 6 and pg. 1 of App. G) BIC and BIPI also incorporate Roxane's Responses to ¶ 51 of the US' SOF re Roxane.

BIC and BIPI do not dispute that Mr. Russillo reported to Mr. Gerstenberg "in his role as president and CEO of BIC" for certain purposes, but dispute that Mr. Russillo reported to him in that role with regard to Roxane pricing and marketing issues or with regard to the furosemide AWP change in 2000. Rather, Mr. Gerstenberg was also the President and COO of Roxane and Mr. Russillo reported to him in that capacity to the extent he discussed Roxane pricing and marketing decisions with him. BIC and BIPI incorporate their Replies to SOF ¶¶ 30, 61, and 71.

BIC and BIPI dispute that "Mr. Russillo consulted with BIC and/or BIPI personnel, including members of the pricing committee, on pricing issues that were regarded as "sensitive" or likely to raise "legal" or "government" issues," as this alleged fact is not supported by the Government's proffered evidence. Mr. Russillo testified only that at his discretion, he "would have asked Werner Gerstenberg, if I thought there was a sensitive AWP issue." (Tab 106, 1/8/09 Russillo Dep. 28-29, 98) Mr. Gerstenberg would have been acting in his capacity as the President and COO of Roxane. (*Id.* at 28-29, 175) Moreover, Mr. Russillo did not testify regarding any actual AWP decision he regarded as "sensitive" that he in fact did discuss with Mr. Gerstenberg. While BIC/BIPI Fauci Exhibit 92 at BOEH01311860 indicates that the "PTC" (which is not defined in the document) only addresses multi-source when "legal," "government," or "administrative issues" were involved,

Mr. Russillo testified that this document was referring to the fact that the Contracts Department that “processed” all orders for Roxane may need to be involved for various administrative reasons, but it was not referring to AWP pricing. (Tab 106, 1/8/09 Russillo Dep. 101-02) BIC and BIPI further state that certain departments at BIPI such as the legal department and the contract administration department provided shared services to both BIPI and Roxane at various times. (BIC/BIPI SOF at ¶ 49) Roxane was charged and paid for the value of the services it used. (*Id.*) Moreover, the Government has not pointed to any evidence that the “PTC” was actually involved with any AWP decisions for any multisource drug at issue in this case. Thus, BIC and BIPI dispute that these alleged facts are material to their motion for summary judgment or the Government’s direct liability or veil-piercing claims against them as they do not demonstrate that BIC or BIPI were involved in setting or reporting AWPs for any Subject Drugs nor do they demonstrate a lack of corporate separateness between BIPI or BIC and Roxane or that BIC or BIPI pervasively controlled Roxane.

BIC and BIPI do not dispute that Mr. Russillo was involved in the decision to raise the AWP on fursoemide in 2000 or that he was aware as of 1999 that there were investigations into allegedly inflated AWPs. BIC and BIPI dispute that Mr. Russillo testified that he “regarded any decision to raise AWPs as ‘sensitive’ and requiring BIC’s approval,” as this alleged fact is not supported by the Government’s proffered evidence. Mr. Russillo testified only that he and Boehringer Ingelheim personnel were sensitive to AWP changes and therefore he “regarded any decision to raise AWPs as needing to be justified.” (Tab 106, 1/8/09 Russillo Dep. 179-80) In addition, Mr. Russillo testified generally regarding Roxane pricing and marketing decisions and specifically with regard to AWP changes that he did not need to seek approval from anyone else; rather, to the extent he raised issues, he raised them to Werner Gerstenberg *at his discretion*. (*Id.* at 28-29 (occasions where he needed Mr. Gerstenberg’s approval “would have been limited. And they would have been at my discretion

to advise him”), 98 (“it would have been at my discretion. I would have asked Werner Gerstenberg, if I thought there was a sensitive AWP issue”), 178-79 (“I did not need approval from Boehringer Ingelheim in Connecticut, unless I felt there were circumstances that I needed to review with Werner Gerstenberg.”)) Indeed, with regard to the only AWP change raised by the Government — the 2000 furosemide change — Mr. Russillo testified after reviewing several documents that he “probably did not” discuss the issue or seek approval from Mr. Gerstenberg. (*Id.* at 191-92) Finally, it is undisputed that Mr. Gerstenberg was both the President and CEO of BIC and the President and COO of Roxane and Mr. Russillo testified that to the extent he consulted Mr. Gerstenberg regarding Roxane pricing and marketing decisions, he did so in Mr. Gerstenberg’s capacity as President and COO of Roxane. (BIC/BIPI SOF at ¶ 30 and United States’ Response to Corrected BIC and BIPI Local 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment filed August 28, 2009 (“US Resp. to BIC/BIPI SOF”) at ¶ 30; Tab 106, 1/8/09 Russillo Dep. 174-75 (if he had consulted with Mr. Gerstenberg regarding the furosemide AWP change, Mr. Gerstenberg “would have been acting as the president of Roxane.”), 28 (“[R]egarding marketing decisions for Roxane’s multisource products,” Mr. Russillo stated that “Werner Gerstenberg was the president of Roxane Laboratories. As such, I had an obligation to keep him informed as to what was going on.”))

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibits 93-96 contain the statements quoted by the Government. The Government’s quotations are selective, incomplete and misleading; the documents in their entirety are the best evidence of their contents. However, even after reviewing all of these documents, Mr. Russillo testified that he could not recall whether he in fact discussed the furosemide AWP change with Mr. Gerstenberg and concluded that “he probably did not.” (Tab 106, 1/8/09 Russillo Dep. 191-92) At least several of the e-mails the Government

references were written by Judy Waterer and Mr. Russillo explained that “I believe Judy was under the impression that I needed approval, and I may have told her that so that she wouldn’t just be bombarding me with requests.” (*Id.* at 177) Moreover, even if Mr. Russillo did seek approval of the furosemide AWP change, he would have consulted with Mr. Gerstenberg and Mr. Gerstenberg “would have been acting as the president of Roxane.” (BIC/BIPI SOF at ¶ 30 and US Resp. to BIC/BIPI SOF at ¶ 30; Tab 106, 1/8/09 Russillo Dep. 174-75, 28-29; *see also* BIC and BIPI’s Reply to SOF ¶ 51)

BIC and BIPI do not dispute that in the email BIC/BIPI Fauci Exhibit 95 Mr. Russillo wrote “[t]o get the approval we need from Conn. though we need some ‘hard’ info.” However, BIC and BIPI dispute that in this email that Mr. Russillo’s reference to Connecticut was meant to refer to BIC or BIPI as the Government implies. In his testimony, when discussing this email, Mr. Russillo explains that he did not need approval from Boehringer Ingelheim in Connecticut unless he felt that he needed to review circumstances with Werner Gerstenberg who was physically located there. (Tab 106, 1/8/09 Russillo Dep. 178-79) As already discussed, Mr. Gerstenberg would have been acting in his role as President and COO of Roxane in this situation. (*Id.* at 174-75) While Mr. Russillo did testify that “Ridgefield, Connecticut, to me meant BIPI,” it was in a completely different context regarding a wholly unrelated document, Exhibit 2 from Mr. Russillo’s 1/8/2009 Deposition testimony, which was a news release put out by BIPI. (*Id.* at 35-36; *see also* Tab 128, Russillo Dep. Ex. 2, 1/28/99 BIPI Press Release) Further, for all of the reasons discussed herein, BIC and BIPI dispute that Mr. Russillo endorsed the furosemide AWP increase only after learning of Mr. Gerstenberg’s position. (*See also* BIC and BIPI’s Reply to SOF ¶ 61) And even if this were true, Mr. Gerstenberg would have been acting in his role as President and COO of Roxane.

Thus, BIC and BIPI dispute that the Government's alleged facts related to the furosemide AWP increase are material to their motion for summary judgment or the Government's direct liability or veil-piercing claims against them as they do not demonstrate that BIC or BIPI were involved in setting or reporting AWP for any Subject Drugs or that BIC or BIPI pervasively controlled Roxane. In addition, BIPI disputes that the Government's alleged facts related to the furosemide AWP increase are material to its motion for summary judgment or the Government's direct liability or veil-piercing claims against it as they relate solely to BIC.

Further, BIC and BIPI dispute that "other BIPI employees recommended marketing strategies for Roxane's multi-source drugs, including to set inflated AWP" as this is not supported by the Government's proffered evidence. First, the Government only provides one instance of one BIPI employee purportedly recommending "marketing strategies" for Roxane products. Second, as "Manager of Reimbursement," Mr. Rowenhorst dealt primarily with resolving adjudication problems with third party payors. (Tab 104, 4/3/03 Rowenhorst Dep. 71-72) These administrative duties fall squarely within the shared services BIPI employees provided to other subsidiaries (*see* BIC/BIPI SOF at ¶ 49), and are far from "marketing strategies" as suggested by the Government. Third, Mr. Rowenhorst explained that his involvement with state Medicaid reimbursement was limited to BIPI, not Roxane. (Tab 104, 4/3/03 Rowenhorst Dep. 71) Fourth, the Government's characterization of the June 2000 *Wall Street Journal* article forwarded by Mr. Rowenhorst is misleading. The portions of the email *not* quoted by the Government make clear that Mr. Rowenhorst's recommendation was that BIPI (not Roxane) "focus on a higher AWP and WAC" for BIPI's *brand* drug Combivent UDV – a product which never came to market and is not one of the subject drugs in this case. (BIC/BIPI Fauci Ex. 97, 6/6/00 Email re UDV Reimbursement Spreadsheet; Tab 105, 10/7/05 Rowenhorst Dep. 80, 162-63) The email was sent to three BIPI

employees (and no Roxane employees) with the subject line “Combivent UDV Spreadsheet,” and attaching that document. (BIC/BIPI Fauci Ex. 97, 6/6/00 Email re UDV Reimbursement Spreadsheet) Mr. Rowenhorst mentions the impact of possible regulations on generic albuterol and ipratropium reimbursement, not for the benefit of Roxane, but because BIPI’s brand drug Combivent competes “with Dey in this market.” (*Id.*) BIC and BIPI dispute that either this alleged fact or BIC/BIPI Fauci Exhibit 97 are material to the Government’s claims against them because they do not relate to Roxane or a Roxane drug at issue.

54. Roxane’s multi-source marketing department recommended the initial launch prices, including AWP, WAC, and direct price for Roxane’s generic drugs. The marketing department was also responsible for developing and recommending changes to these prices for Roxane’s generic drugs. In coordination with the contracts department, the marketing department developed pricing guidelines that established the range of contract prices that could be offered to customers and would assist in developing prices for bids outside of the pre-established grid. (Tab 27, 4/1/03 Waterer Dep. 517-518; Tab 29, 5/11/07 Waterer Dep. 566-567; Tab 31, 12/12/08 Waterer Dep. 47-49; Tab 18, 7/26/07 Paoletti Dep. 110-111; Tab 7, 6/25/02 Feldman Dep. 48, 56, 79-80; Tab 9, 11/18/05 Feldman Dep. 49-50; Tab 30, 7/24/07 Waterer Dep. 869-871; Tab 19, 10/11/05 Powers Dep. 51-52; Tab 16, 9/20/05 Paoletti Dep. 32)

United States’ Response: The United States does not dispute that employees in Roxane’s multi-source marketing department, including Ms. Waterer and Ms. Paoletti, recommended initial launch prices for some of Roxane’s multi-source drugs. The United States disputes this paragraph, however, to the extent it implies that Ms. Waterer and Ms. Paoletti were exclusively responsible for these activities, or that BIC and/or BIPI were not actively involved in the conduct for which the United States is seeking damages. (*See supra* United States’ Responses to Paragraphs 7, 8, 14, 51 and 53)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). To the extent the Government’s response is anything other than an unqualified admission, BIC and BIPI object to the Government’s response because it is not clear what material facts, if any, it is disputing. BIC and BIPI dispute that BIC and/or BIPI were actively involved in the activities

described in this paragraph or in the conduct for which the United States is seeking damages. (*See* BIC and BIPI's Replies to SOF ¶¶ 7, 8, 14, 51 and 53)

55. The marketing department's pricing recommendations were circulated to various Roxane employees for information and sign-off purposes. The positions and particular individuals included changed over time, but generally included some combination of the product manager, director of multi-source marketing, a member of the finance department, a member of the contracts department, a member of the sales department, and someone in senior management at Roxane, such as Roxane's Vice-President of Sales and Marketing. Examples of Roxane employees in those positions include Lesli Paoletti, Judy Waterer, John Swartz, John Powers, Rich Feldman, and Ed Tupa. (Tab 17, 11/30/05 Paoletti Dep. 16-17, 90-91; Tab 28, 11/28/05 Waterer Dep. 168 (marketing would recommend the pricing and it would get routed and approved by management); Tab 26, 10/24/01 Waterer Dep. 34-38 (price routing forms included marketing management, sales management, contracts management, and sometimes member of senior management, such as Gerald Wojta, President of Roxane); Tab 29, 5/11/07 Waterer Dep. 602-603, 619-621, 624) Other than being circulated to this core set of Roxane employees, prices for Roxane's multi-source drugs never went to a formal pricing committee for approval. (Tab 20, Russillo Dep. 147-148)

United States' Response: The United States does not dispute that pricing recommendations for Roxane's multi-source products were circulated among Ms. Paoletti, Ms. Waterer, Mr. Swartz, Mr. Powers, Mr. Feldman and Mr. Tupa. The United States disputes this paragraph, however, to the extent it implies that this group of employees was exclusively responsible for pricing and marketing Roxane's multi-source products, or that BIC and/or BIPI were not actively involved in the conduct for which the United States is seeking damages. (*See supra* United States' Responses to Paragraphs 7, 8, 14, 51 and 53) Further answering, the pricing committee became involved with multi-source pricing when "legal" or "government" issues were implicated. (BIC/BIPI Fauci Exhibit 92 at BOEH01311860)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). To the extent the Government's response is anything other than an unqualified admission, BIC and BIPI object to the Government's response because it is not clear what material facts, if any, it is disputing. BIC and BIPI dispute that BIC and/or BIPI were actively involved in the activities described in this paragraph or in the conduct for which the United States is seeking damages. (*See* BIC and BIPI's Replies to SOF ¶¶ 7, 8, 14, 51 and 53)

BIC and BIPI do not dispute that BIC/BIPI Fauci Exhibit 92 at BOEH01311860 indicates that the “PTC” (which is not defined in the document) only addressed multi-source when “legal,” “government,” or “administrative issues” were involved. BIC and BIPI dispute that BIC/BIPI Fauci Exhibit 92 at BOEH01311860 makes any mention of the “PTC” being involved in multi-source “pricing.” Moreover, BIC and BIPI dispute that this fact is material to their motion for summary judgment or the Government’s claims against them as the Government has not shown that the “PTC” was actually involved with any AWP decision for any multisource drug at issue in this case. Indeed, Mr. Russillo testified that this document was referring to the fact that the Contracts Department that “processed” all orders for Roxane may need to be involved for various administrative reasons, but it was not referring to AWP pricing. (Tab 106, 1/8/09 Russillo Dep. 101-03) BIC and BIPI further state that certain departments at BIPI such as the legal department and the contract administration department provided shared services to both BIPI and Roxane at various times. (BIC/BIPI SOF at ¶ 49) Roxane was charged back and paid for the value of the services it used. (*Id.*)

56. Until 1998, Ms. Waterer reported to Ed Tupa, Vice-President of Marketing at Roxane. (Tab 26, 10/24/01 Waterer Dep. 57) While Mr. Tupa had a functional reporting relationship to Mr. Berkle, Vice President of the Business Unit Ethical Pharmaceuticals, Mr. Tupa led Roxane’s marketing department, with Ms. Waterer handling the day-to-day marketing and pricing activities for Roxane’s products. Mr. Berkle’s role was limited to very high level strategic oversight. (Tab 26, 10/24/01 Waterer Dep. 31-34; Tab 2, 10/31/08 Berkle Dep. 50-51; *id.* 76 (“I was not involved in the day-to-day operations of Roxane or in basically how they set their prices in general or how they marketed their generic drugs”); *id.* 125 (“In general I’ve said to you before that I really did not get involved in the details of pricing for the generic products within the Roxane line”); Tab 61, 10/31/08 Berkle Dep. Ex. 5, RLI-AWP-00162482-84 at 83 (5/3/96 Roxane Sales and Marketing Reorganization Announcement and Organizational Chart) (1996 Reorganization Announcement) (“The Roxane Marketing & Sales Department will be led by Mr. Edward Tupa, who currently has this responsibility.”); Tab 62, RLI-ORG00000068 (Jan. 1998 Organigram); Tab 59, RLIIORG00000080 (1996 Budget Organizational Chart))

United States’ Response: The United States does not dispute that Ms. Waterer reported to Mr. Tupa for a period of time, or that Mr. Tupa “functionally” reported to Mr. Berkle. The United States disputes, however, that Mr. Berkle’s “role was limited to very high level strategic oversight.” Further answering, Mr. Berkle had detailed involvement in the marketing of Roxane’s branded generic products, including approving marketing plans and pricing. (*See infra*

United States' Response to Paragraph 51) Mr. Berkle also was involved in Roxane's marketing of multi-source products, including reviewing proposed marketing strategies, (*see* United States' Responses to Paragraphs 7 and 53), and reviewing bids to important customers such as Premier and Cardinal Health. (*See, e.g.*, BIC/BIPI Fauci Exhibit 73; BIC/BIPI Fauci Exhibit 42) In addition, other BIPI employees (including Mr. Rowenhorst) participated in marketing decisions for Roxane's multi-source products. (BIC/BIPI Fauci Exhibit 97)

BIC and BIPI's Reply: The Government does not dispute that Ms. Waterer reported to Mr. Tupa until 1998 or that Mr. Tupa had a functional reporting relationship to Mr. Berkle, and therefore those facts are deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). The Government also does not dispute, and its additional facts do not contradict, that Mr. Tupa led Roxane's marketing department, with Ms. Waterer handling the day-to-day marketing and pricing activities for Roxane's products, and therefore those facts are deemed admitted.

BIC and BIPI dispute that "Mr. Berkle had detailed involvement in the marketing of Roxane's branded generic products, including approving marketing plans and pricing" and that "Mr. Berkle also was involved in Roxane's marketing of multi-source products, including reviewing proposed marketing strategies." (*See* BIC and BIPI's Replies to SOF ¶¶ 7, 51, and 53) BIC and BIPI also dispute that Mr. Berkle was involved in the marketing of Roxane's multisource products by "reviewing bids to important customers such as Premier and Cardinal Health" as the Government's proffered evidence does not support this fact. BIC/BIPI Fauci Exhibit 73 does not even relate to bids to Cardinal Health regarding Roxane's multisource products. Rather it is an e-mail from Mr. Tupa, a Roxane employee, to Mr. Berkle regarding a meeting Mr. Tupa had with Cardinal "to discuss the development of our mutual businesses." It discusses the "concept" of negotiating at the "Corporate level" with Cardinal, but indicates that "all aspects of each company" would be considered and that a "team representing various BIC business interests" should be formed

if the concept will be pursued. (BIC/BIPI Fauci Ex. 73, 9/22/97 Email re Cardinal Health) There is nothing in this e-mail to indicate that Mr. Berkle would be involved with marketing or pricing of Roxane's multi-source products, nor is it inconsistent with Roxane's assertion that Mr. Berkle was only involved in high level strategic oversight. Similarly, BIC/BIPI Fauci Exhibit 42 is a memorandum that discusses the business interests of all of the Boehringer U.S. entities, with relation to Premier, and was sent to "update" Mr. Berkle on the general approach that John Powers, a Roxane employee, was going to take with respect to Premier. (BIC/BIPI Fauci Ex. 42, 2/27/98 Inter-office memo re PREMIER) There is nothing in this memorandum to indicate that Mr. Berkle was involved in setting or approving the bid prices for or marketing Roxane's multisource products, nor is it inconsistent with Roxane's assertion that Mr. Berkle was only involved in high level strategic oversight.

BIC and BIPI dispute that "other employees, including Mr. Rowenhorst, participated in marketing decisions for Roxane's multi-source products" as that alleged fact is not supported by the Government's proffered evidence. The Government only cites to BIC/BIPI Fauci Exhibit 97, which is an email that does not relate to Roxane or a Roxane drug at issue. Rather, this email was sent to three BIPI employees with the subject line "Combivent UDV Spreadsheet," and attaching that document. (BIC/BIPI Fauci Ex. 97, 6/6/00 Email re UDV reimbursement spreadsheet) Combivent UDV is a BIPI brand product, a product which never came to market and is not one of the subject drugs in this case. (Tab 105, 10/7/05 Rowenhorst Dep. 80, 162-63) Mr. Rowenhorst mentions the impact of possible regulations on generic albuterol and ipratropium reimbursement, not for the benefit of Roxane, but because BIPI's brand drug Combivent competes "with Dey in this market." (BIC/BIPI Fauci Ex. 97, 6/6/00 email re UDV reimbursement spreadsheet) BIC and BIPI dispute that either this statement of fact or BIC/BIPI Fauci Exhibit 97 are material to their motion for

summary judgment or the Government's claims against them because they do not relate to a Roxane drug at issue.

In addition, BIC and BIPI dispute that the Government's additional facts are relevant to their motion for summary judgment or the Government's claims against them because to the extent Mr. Berkle was involved in pricing or marketing issues regarding Roxane's products, he was acting in his role as Vice-President of Business Unit Ethical Pharmaceuticals and on behalf of Roxane, not BIPI. Further, BIC disputes that the Government's additional facts are material to its motion for summary judgment or the Government's claims against it because they relate solely to BIPI.

57. Ed Tupa left his position as Vice President of Marketing in October 1998. Tom Russillo, who was the President of another BIC subsidiary, Ben Venue Laboratories, Inc. ("BVL"), took on the additional position of head of Multisource Marketing for Roxane at that time. (Tab 63, 10/31/08 Berkle Ex. 27 RLI-AWP-00161738-40 (10/23/98 Reorganization Memo); Tab 20, Russillo Dep. 23-26; Tab 32, RLI-ORG00000016 (Jan. 1998 Organigram)) Mr. Russillo reported to Werner Gerstenberg. (Tab 20, Russillo Dep. 29)

United States' Response: Undisputed. Further answering, Mr. Russillo's "responsibility for Roxane's multi-source business [wa]s not well recognized in the industry." (BIC/BIPI Fauci Exhibit 98)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). BIC and BIPI dispute that the Government's second sentence is material to their motion for summary judgment or the Government's claims against them.

58. Ms. Waterer and others in the Roxane multi-source marketing department began reporting to Mr. Russillo in this new role. (Tab 63, 10/31/08 Berkle Ex. 27 at RLI-AWP-00161738-40 (10/23/98 Memo); Tab 26, 10/24/01 Waterer Dep. 57; Tab 20, Russillo Dep. 49- 50, 53-54; Tab 58, D0530608 (2003 Multisource Sales & Marketing Organizational Chart))

United States' Response: Undisputed. Further answering, *see supra* United States' Response to Paragraphs 7, 8, 14, 51 and 53.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI incorporate their Replies to ¶¶ 7, 8, 14, 51 and 53.

59. Mr. Russillo had worked in the generic pharmaceutical business for many years and Ben Venue’s generic sales division, Bedford Laboratories, was very successful in the market. Thus, Mr. Russillo had extensive experience and expertise in marketing and selling generic drugs that he could bring to bear to help build Roxane’s generic business. (Tab 20, Russillo Dep. 26, 202-203)

United States’ Response: Undisputed. Further answering, *see supra* United States’ Response to Paragraphs 7, 8, 14, 51 and 53.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI incorporate their Replies to ¶¶ 7, 8, 14, 51 and 53.

60. Mr. Russillo “ultimately managed” the pricing approval process for Roxane’s multi-source drugs from late 1998 forward. (*Id.* 53-54, 286) Ms. Waterer and the Roxane marketing department, however, continued to be responsible on a day to day basis for setting the AWP for multi-source products. (*Id.* 49-50, 54 (“For the most part, I would not be personally involved. Judy would propose an AWP; and for the most part, I would have approved it.”); Tab 26, 10/24/01 Waterer Dep. 57, 168-170)).

United States’ Response: The United States disputes this paragraph to the extent it implies that BIC and/or BIPI were not involved in the conduct for which the United States is seeking damages. Further answering, *see infra* United States’ Responses to Paragraphs 7, 8, 14, 51 and 53.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

parties.”). To the extent the Government’s response is anything other than an unqualified admission, BIC and BIPI object to the Government’s response because it is not clear what material facts, if any, it is disputing. BIC and BIPI incorporate their Replies to ¶¶ 7, 8, 14, 51 and 53.

61. Although Mr. Russillo was able to approve or disapprove AWP and price recommendations without further routing to other Roxane employees, Ms. Waterer continued to circulate price proposals to key Roxane employees. (Tab 29, 5/11/07 Waterer Dep. 596; *see also*, *e.g.*, Tab 64, RLI-AWP-00559612 (Feb. 19, 2002 Price Approval form); Tab 65, RLI-AWP-00081519 (April 1, 2002 Price Approval form); Tab 66, RLI-AWP-00083025-30 (Feb. 20, 2003 Price Approval form); Tab 67, BOEH01140848 (May 28, 2003 Price Approval form); Tab 68, RLI-AWP-00082794-09 (June 4, 2003 Price Approval form); Tab 69, RLI-AWP-00081645- 51 (July 2, 2003 Price Approval Email Chain))

United States’ Response: The United States disputes that Mr. Russillo approved raising Roxane’s AWP on his own. Mr. Russillo testified that he only supported raising the AWP for furosemide *after* establishing Mr. Gerstenberg’s position. (*See infra* United States’ Response to Paragraph 53; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 172:18 - 174:3, 192:11 - 194:3, 222:21 - 223:1) Further answering, Mr. Russillo made clear that Boehringer Ingelheim’s approval was required prior to raising the furosemide AWP. (*See, e.g.*, BIC/BIPI Fauci Exhibit 95)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). The Government’s additional facts do not controvert BIC and BIPI’s statement of fact and do not create a disputed issue of fact material to their motion for summary judgment.

BIC and BIPI dispute that Mr. Russillo testified that “he only supported raising the AWP for furosemide *after* establishing Mr. Gerstenberg’s position” as it is not supported by the Government’s proffered evidence. Mr. Russillo specifically testified that he could not recall whether he consulted with Mr. Gerstenberg about the furosemide AWP change and concluded, after reviewing various documents, that he “probably did not.” (Tab 106, 1/8/09 Russillo Dep. 173-75, 191-92) In addition, Mr. Russillo made clear that as a general rule when he made a marketing decision or an AWP

decision on a Roxane multi-source product he did not need approval from Mr. Gerstenberg; to the extent he raised issues with Mr. Gerstenberg it was “at [his] discretion.” (*Id.* at 28-29, 98) BIC and BIPI also dispute that “Mr. Russillo made clear that Boehringer Ingelheim’s approval was required prior to raising the furosemide AWP” as that alleged fact is not supported by the Government’s proffered evidence. While BIC/BIPI Fauci Exhibit 95 states that “[t]o get the approval we need from Conn. though we need some ‘hard’ info,” Mr. Russillo explained that “I did not need approval from Boehringer Ingelheim in Connecticut unless I felt there were circumstances that I needed to review with Werner Gerstenberg,” who was physically located there. (*Id.* at 178-179) Mr. Russillo further testified after reviewing the Government’s cited document and several others related to the furosemide AWP change that he “probably did not” discuss the issue or seek approval from Mr. Gerstenberg. (*Id.* at 191-92) BIC and BIPI also incorporate their Reply to ¶ 53.

Moreover, even if true, the Government’s additional facts are immaterial to BIC and BIPI’s motion for summary judgment and the Government’s claims against them because it is undisputed that Mr. Gerstenberg was both the President and CEO of BIC and the President and COO of Roxane in 2000 and Mr. Russillo testified that, if he had consulted with Mr. Gerstenberg regarding the furosemide AWP change, Mr. Gerstenberg “would have been acting as the president of Roxane.” (BIC/BIPI SOF at ¶ 30 and US Resp. to BIC/BIPI SOF at ¶30; Tab 106, 1/8/09 Russillo Dep. 175) Indeed, when asked who he reported to “regarding marketing decisions for Roxane’s multisource products,” Mr. Russillo stated that “Werner Gerstenberg was the president of Roxane Laboratories. As such, I had an obligation to keep him informed as to what was going on.” (Tab 106, 1/8/09 Russillo Dep. 28) In addition, BIPI disputes that the Government’s additional facts are material to its motion for summary judgment or the Government’s claims against it as they relate solely to BIC.

62. Mr. Russillo generally did have to seek further approval from his superiors regarding Roxane multi-source prices. Rather, at his discretion, he may have consulted Werner Gerstenberg, who was the President of Roxane. (Tab 20, Russillo Dep. 98)

United States' Response: Disputed. Mr. Russillo testified that he only supported raising the furosemide AWP's *after* establishing Mr. Gerstenberg's position. (*See infra* United States' Response to Paragraph 53; BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 172:18 - 174:3, 192:11 - 194:3, 222:21 - 223:1) Further answering, Mr. Russillo made clear that Boehringer Ingelheim's approval was required. (*See, e.g.*, BIC/BIPI Fauci Exhibit 95)

BIC and BIPI's Reply: The Government's response does not create a disputed issue of fact material to BIC and BIPI's motion. While the Government claims to dispute this paragraph, its alleged facts regarding one price change do not controvert Mr. Russillo's undisputed testimony regarding his general practice. Thus, this fact should be deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

BIC and BIPI dispute that Mr. Russillo testified that "he only supported raising the AWP's for furosemide *after* establishing Mr. Gerstenberg's position" as it is not supported by the Government's proffered evidence. Mr. Russillo specifically testified that he could not recall whether he consulted with Mr. Gerstenberg about the furosemide AWP change and concluded, after reviewing various documents, that he "probably did not." (Tab 106, 1/8/09 Russillo Dep. 173-75, 191-92) In addition, Mr. Russillo made clear that as a general rule when he made a marketing decision or an AWP decision on a Roxane multi-source product he did not need approval from Mr. Gerstenberg; to the extent he raised issues with Mr. Gerstenberg it was "at [his] discretion." (*Id.* at 28-29, 98) BIC and BIPI also dispute that "Mr. Russillo made clear that Boehringer Ingelheim's approval was required prior to raising the furosemide AWP's" as that alleged fact is not supported by the Government's proffered evidence. While BIC/BIPI Fauci Exhibit 95 states that "[t]o get the approval we need from

Conn. though we need some ‘hard’ info,” Mr. Russillo explained that “I did not need approval from Boehringer Ingelheim in Connecticut unless I felt there were circumstances that I needed to review with Werner Gerstenberg,” who was physically located there. (*Id.* at 178-79) Mr. Russillo further testified after reviewing the Government’s cited document and several others related to the furosemide AWP change that he “probably did not” discuss the issue or seek approval from Mr. Gerstenberg. (*Id.* at 191-192) BIC and BIPI also incorporate their Reply to ¶ 53.

Moreover, even if true, the Government’s additional facts are immaterial to BIC and BIPI’s motion for summary judgment and the Government’s claims against them because it is undisputed that Mr. Gerstenberg was both the President and CEO of BIC and the President and COO of Roxane in 2000 and Mr. Russillo testified that, if he had consulted with Mr. Gerstenberg regarding the furosemide AWP change, Mr. Gerstenberg “would have been acting as the president of Roxane.” (BIC/BIPI SOF at ¶ 30 and US Resp. to BIC/BIPI SOF at ¶ 30; Tab 106, 1/8/09 Russillo Dep. 175) Indeed, when asked who he reported to “regarding marketing decisions for Roxane’s multisource products,” Mr. Russillo stated that “Werner Gerstenberg was the president of Roxane Laboratories. As such, I had an obligation to keep him informed as to what was going on.” (Tab 106, 1/8/09 Russillo Dep. 28) In addition, BIPI disputes that the Government’s additional facts are material to its motion for summary judgment or the Government’s claims against it as they relate solely to BIC.

63. After Roxane’s management signed-off on initial prices or price changes for Roxane’s generic products, someone from Roxane’s marketing or trade relations departments would report the pricing information to third party compendia, such as First Data Bank. (Tab 27, 4/1/03 Waterer Dep. 501-502, 581; Tab 29, 5/11/07 Waterer Dep. 682-86; Tab 17, 11/30/05 Paoletti Dep. 47-49; Tab 70, 5/10/07 Waterer Dep. Ex. 24 (Red Book 13858-59); Tab 71, 5/10/07 Waterer Dep. Ex. 25 (Red Book 13860-13864); Tab 72, 5/10/07 Waterer Dep. Ex. 26 (Red Book 13865-13867); Tab 73, 5/10/07 Waterer Dep. Ex. 27 (Red Book 13868-13870); Tab 74, 5/10/07 Waterer Dep. Ex. 29 (Red Book 13969-13971); Tab 75, 5/10/07 Waterer Dep. Ex. 30 (Red Book 13972-13974); Tab 76, 5/10/07 Waterer Dep. Ex. 31 (Red Book 13975-76); Tab 77, 5/10/07 Waterer Dep. Ex. 34 (Red Book 14071-14083); Tab 78, 5/10/07 Waterer Dep. Ex. 35 (Red Book 14084-14085); Tab 79, 5/10/07 Waterer Dep. Ex. 42 (Red Book 14185- 14186); Tab 80, 5/10/07 Waterer Dep. Ex. 47 (Red Book 14205-14206); Tab 81, 11/17/04 Feldman Dep. Ex. 93 TXEX00520)

United States' Response: The United States disputes the first sentence of this paragraph to the extent it implies that BIC and/or BIPI did not actively participate in decisions to approve inflated AWP's for Roxane's drugs. The United States does not dispute that employees in the marketing and Trade Relations departments reported pricing information for Roxane's multi-source products (including AWP's) to third party pricing compendia. Specifically, prior to 2001, the Trade Relations Department was responsible for reporting AWP's to third party pricing compendia; after 2001, Ms. Paoletti in the marketing department took over this responsibility. (BIC/BIPI Fauci Exhibit 99 (11/30/2005 Paoletti Dep.) at 48:15 - 50:9; BIC/BIPI Fauci Exhibit 100 (9/20/2005 Paoletti Dep.) at 81:15 - 82:24)

Further answering, prior to 2001, the Trade Relations Department was responsible for *both* Roxane and BIPI products. (*See, e.g.*, BIC/BIPI Fauci Exhibit 34 (11/17/2004 Feldman Dep.) at 108:24 - 109:25; BIC/BIPI Fauci Exhibit 35 (1/25/05 Gordon Dep.) at 19:14 - 21:9; BIC/BIPI Fauci Exhibit 37 (12/2/2005 Mike Doan Dep.) at 43:19 - 44:8; BIC/BIPI Fauci Exhibit 38 (11/22/2005 Anthony Tavoraro Dep.) at 57:17 - 59:1) As the Executive Director of the Trade Relations Department, Richard Feldman reported AWP's to pricing compendia for both Roxane and BIPI products. (*See* BIC/BIPI Fauci Exhibit 105)

Moreover, BIPI personnel were responsible for reporting AWP's to the pricing compendia for Roxane's branded and branded generic products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.) at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). The Government's additional facts do not controvert BIC and BIPI's statement of fact and do not create a disputed issue of fact material to their motion for summary judgment. BIPI and BIC do not dispute that Richard Feldman in the Trade Relations department handled the reporting of AWP's for Roxane's multisource products to third party pricing compendia during a period of time leading up to around 2001 when he left Roxane, and that Lesli Paoletti began to report the AWP's to third party pricing compendia when Richard Feldman left. (BIC/BIPI Fauci Ex. 99, 11/30/05 Paoletti Dep. 48-50; BIC/BIPI Fauci Ex. 100, 9/20/05 Paoletti Dep. 81-82)

BIC and BIPI do not dispute that prior to 2001, Roxane's Trade Relations department had some responsibility for both Roxane and BIPI products. However, Roxane's Trade Relations department primarily focused on Roxane products and only worked with BIPI products on a very limited basis. (Tab 96, 11/4/05 Gordon Dep. 35) As Mr. Sykora explained, Roxane's National Account Managers did not "actively promote[]" and "weren't selling" BIPI's products, but rather, at times, they "helped on the launch of the brand [BIPI] products" in that they would discuss the launch with wholesalers and "provide them information so they could make purchase orders." (Tab 109, 12/4/08 Sykora Dep. 50-52) Mr. Sykora further explained why it made sense for Roxane's Trade Relations group to provide this assistance: "Boehringer Ingelheim's a brand company only. Rather than have a national accounts group that they may only need two or three times a year during a new product launch, it made sense to utilize a subsidiary's existing national accounts department during those time when they needed it." (*Id.*) BIC and BIPI do not dispute that Richard Feldman, while a Roxane employee, at times reported AWP's to pricing compendia for both Roxane and BIPI products. However, as the evidence cited by the Government indicates, when Mr. Feldman reported Roxane prices he generally did so using Roxane letterhead and in his position as the Executive Director of Trade and Pharmacy Affairs for Roxane and when he reported BIPI prices he did so using BIPI letterhead and as the Executive Director of BIPI's Trade Relations department. (BIC/BIPI Fauci Ex. 105, Product Announcements and Reporting to Compendia)

BIC and BIPI dispute that these additional facts are material to their motion for summary judgment or the Government's direct liability claims against them as they do not support that BIC or BIPI were involved in setting or reporting Roxane's AWP's. In addition, the Government's additional facts are immaterial to the Government's veil-piercing claims against BIPI and BIC because it involves Roxane and Roxane employees offering assistance to BIPI, and does not support

that BIPI or BIPI employees were involved with or exerting control over Roxane's business, nor does it detract from Roxane and BIPI's separate corporate identities given each company had separate and distinct products and it would be clear whose products were being promoted or reported. In addition, BIC disputes that these facts are material to its motion for summary judgment or the Government's claims against it as the facts relate solely to BIPI.

BIC and BIPI dispute that "BIPI personnel were responsible for reporting AWP's to the pricing compendia for Roxane's branded and branded generic products" as this fact is not supported by the Government's proffered evidence, BIC/BIPI Fauci Exhibit 52. In his testimony, Mr. Ciarelli does not testify that BIPI personnel reported AWP's to the pricing compendia for Roxane's branded and branded generic products. Rather, Mr. Ciarelli testifies that "one of the people in Roxane who reported to me, John Powers, reported those prices." (BIC/BIPI Fauci Ex. 52, 7/25/07 Ciarelli Dep. 24) Moreover, to the extent that Mr. Ciarelli may have had any involvement in reporting prices for Roxane's brand and branded generic products, it is immaterial to BIC and BIPI's motion for summary judgment and the Government's direct liability claims against them as Mr. Ciarelli was acting on behalf of Roxane pursuant to the role and responsibilities he had been given for Roxane's brand and branded generic products and therefore his conduct cannot be imputed to BIPI. (Tab 63, 10/23/98 Reorganization Memo at 4; BIC/BIPI Fauci Ex. 52, 7/25/07 Ciarelli Dep. 22-23) Moreover, Mr. Ciarelli's role with regard to Roxane's branded generic products is immaterial to BIC and BIPI's motion for summary judgment and the Government's veil-piercing claims against them because it is common for affiliated companies to have overlapping managers and the evidence does not suggest that Mr. Ciarelli exercised pervasive control over any part of Roxane's business. In addition, BIC disputes that this additional fact is relevant to its motion for summary judgment or the Government's claims against it because it relates solely to BIPI.

64. At times, Roxane received requests from third party compendia to verify its reported AWP's and WAC's. Roxane's marketing department was responsible for reviewing the information and communicating any changes or corrections to the compendia. (Tab 29, 5/10/07 Waterer Dep. 455-458; Tab 18, 7/26/07 Paoletti Dep. 195-197; Tab 82, 5/9/07 Waterer Dep. Ex. 32 (Red Book 13977-14065))

United States' Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

65. Roxane had National Account Managers ("NAMs") who handled day-to-day marketing and sales interactions with Roxane's customers, including wholesalers and chains. (Tab 23, Sykora Dep. 200-202; Tab 8, 11/17/04 Feldman Dep. 86-87)

United States' Response: The United States does not dispute that NAMs promoted Roxane's products. Further answering, the NAMs were in the Trade Relations Group which, prior to 2001, had responsibility for promoting both Roxane and BIPI products. (*See, e.g.*, BIC/BIPI Fauci Exhibit 34 (11/17/2004 Feldman Dep.) at 108:24 - 109:25; BIC/BIPI Fauci Exhibit 35 (1/25/2005 Gordon Dep.) at 19:14 - 21:9; BIC/BIPI Fauci Exhibit 37 (12/2/2005 Doan Dep.) at 43:19 - 44:8; BIC/BIPI Fauci Exhibit 38 (11/22/2005 Tavolaro Dep.) at 57:17 - 59:1)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

The Government's additional facts do not controvert BIC and BIPI's statement of fact and do not create a disputed issue of fact material to their motion for summary judgment.

BIC and BIPI do not dispute that prior to 2001, Roxane's Trade Relations department had some responsibility for both Roxane and BIPI products. However, Roxane's Trade Relations department primarily focused on Roxane products and only worked with BIPI products on a very

limited basis. (Tab 96, 11/4/05 Gordon Dep. 35) As Mr. Sykora explained, Roxane's National Account Managers did not "actively promote[]" and "weren't selling" BIPI's products, but rather at times they "helped on the launch of the brand [BIPI] products" in that they would discuss the launch with wholesalers and "provide them information so they could make purchase orders." (Tab 109, 12/4/08 Sykora Dep. 50-52) Mr. Sykora further explained why it made sense for Roxane's Trade Relations group to provide this assistance: "Boehringer Ingelheim's a brand company only. Rather than have a national accounts group that they may only need two or three times a year during a new product launch, it made sense to utilize a subsidiary's existing national accounts department during those time when they needed it." (*Id.*)

BIC and BIPI dispute that the Government's additional fact is material to their motion for summary judgment or the Government's direct liability claims against them as it is unrelated to the setting or reporting of Roxane's AWP's. In addition, the Government's additional fact is immaterial to the Government's veil-piercing claims against BIPI and BIC because it involves Roxane offering assistance to BIPI, and does not support that BIPI was involved in or exerted control over Roxane's business, nor does it detract from Roxane's and BIPI's separate corporate identities given each company had separate and distinct products and it would be clear whose products were being promoted. In addition, BIC disputes that this fact is material to its motion for summary judgment or the Government's claims against it as the facts relate solely to BIPI.

66. Based on their knowledge of market conditions, NAMs would provide the marketing department with recommendations for price changes as the competitive landscape for certain drugs changed. The marketing department would compile relevant information and develop a final pricing recommendation. (Tab 23, Sykora Dep. at 76-77; Tab 28, 11/28/05 Waterer Dep. at 32-35)

United States' Response: Undisputed. Further answering, *see supra* United States Response to Paragraph 65.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI incorporate their Reply to ¶ 65.

67. In June 1996, Roxane launched ipratropium bromide, a generic version of BIPI's brand product Atrovent. (Tab 26, 10/24/01 Waterer Dep. 38-39; Tab 29, 5/10/07 Waterer Dep. 292-294; Tab 25, 10/18/05 Via Dep. 61)

United States' Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

68. Tom Via, a Roxane marketing employee, developed the marketing plan for ipratropium bromide. As part of that process, Mr. Via and Ed Tupa, Roxane's Vice President of Sales and Marketing set the AWP, WAC, and direct prices for ipratropium bromide at the product's launch. (Tab 25, 10/18/05 Via Dep. 154-155, 157, 163-165) The AWP for Roxane's ipratropium bromide did not change from launch until the product was discontinued in 2004. (Tab 83, Roxane's Second Supp. Objections and Answers to the Commonwealth's First Set of Interrogatories (7/18/07) at 3)

United States' Response: The United States does not dispute that Mr. Via and Mr. Tupa participated in the development of the ipratropium bromide marketing plan. The United States disputes this paragraph to the extent it implies that Mr. Via and Mr. Tupa were exclusively responsible for the ipratropium bromide marketing plan. As noted *supra* in the United States' Responses to Paragraphs 7 and 53, Mr. Tupa testified that Mr. Berkle was involved in the decision to approve the ipratropium bromide marketing plan. (BIC/BIPI Fauci Exhibit 25 (1/31/2003 Tupa Dep.) at 36:15 - 37:17) Moreover, BIPI employees met with Roxane employees regarding marketing strategies for ipratropium bromide, including at a January 1996 meeting where it was agreed that the AWP for ipratropium bromide would be set at 10% less than Atrovent's AWP. (BIC/BIPI Fauci Exhibit 24, at RLI-AWP-00299558)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). The Government’s additional facts do not controvert BIC and BIPI’s statement of fact and do not create a disputed issue of fact material to their motion for summary judgment.

BIC and BIPI dispute that “Mr. Tupa testified that Mr. Berkle was involved in the decision to approve the ipratropium bromide marketing plan” as it is not supported by the Government’s proffered evidence. Mr. Tupa testified only that “the president of the company would be involved, and I – I – I *believe* Mr. Berkle had been involved as well.” (BIC/BIPI Fauci Ex. 25, 1/31/03 Tupa Dep. 37 (emphasis added)) In addition, Mr. Berkle testified that he did not recall approving the marketing plan for ipratropium bromide and that “I would not have had access necessarily to the detailed marketing plan. I was concerned with the overall forecasts and general strategies, but not in the nitty-gritty of the marketing plan. Mr. Wojta [the President and COO of Roxane at the time] really had the responsibility and the authority to approve that.” (Tab 89, 1/27/05 Berkle Dep. 107) Further, the AWP launch figure was only a small piece of the overall marketing plan prepared by Mr. Via and Mr. Berkle who unequivocally testified that “anything to do with the establishment of pricing [for ipratropium bromide] was decided within the Roxane organization, had to be approved by the CEO of the Roxane – or the president of the Roxane organization.” (*Id.* at 72-73; *see also* Tab 90, 10/31/08 Berkle Dep. 77-78 (“I was not involved in the marketing or pricing of Ipratropium Bromide.”)) Indeed, the AWP for ipratropium bromide was set at 10% below the brand according to standard practice at Roxane and within the industry and thus there was little to decide or discuss

regarding ipratropium bromide's AWP, especially with a brand drug company like BIPI. (*See* Roxane SOF at ¶ 99)

BIC and BIPI do not dispute that BIPI and Roxane employees met and discussed the launch of Roxane's ipratropium bromide product at a meeting that appears from BIC/BIPI Fauci Exhibit 24 to have occurred in January 1996, as it would make sense such discussions would occur given that Roxane's ipratropium bromide product was the first generic version of BIPI's drug Atrovent. (Tab 110, 10/18/05 Via Dep. 60-61; *see also* Tab 90, 10/31/08 Berkle Dep. 78-79 (there was no coordination between BIPI and Roxane regarding how ipratropium bromide was marketed except "[i]n the sense that we were sister companies and there was discussions between the two companies relative to the experience that BIPI had in the marketing with Atrovent.")) However, BIC and BIPI dispute any implication that there was more than one meeting between BIPI and Roxane employees, or that the meeting participants discussed anything beyond a general ipratropium bromide market overview. (Tab 110, 10/18/05 Via Dep. 66; BIC/BIPI Fauci Ex. 24, Ipratropium Bromide UDV Generic Launch Meeting Summary; Tab 89, 1/27/05 Berkle Dep. 28 ("there was cross fertilization of general information about our experiences with Atrovent.")) BIC and BIPI dispute that BIPI personnel provided any input in or "agreed to" setting the launch AWP for ipratropium bromide at 10% less than Atrovent's at the January 1996 meeting as the Government's proffered evidence does not support that alleged fact. BIC/BIPI Fauci Exhibit 24 merely reflects that "[i]t should be noted that the AWP for IBUDV will be 10% below Atrovent's AWP at the time of launch," implying this had already been determined by Roxane. (BIC/BIPI Fauci Ex. 24, Ipratropium Bromide UDV Generic Launch Meeting Summary at ROX 04291-92)

Thus, BIC and BIPI dispute that these facts are material to their motion for summary judgment at they do not create a genuine issue of fact regarding BIC or BIPI's involvement in setting

or reporting the AWP for ipratropium bromide and do demonstrate a lack of corporate separateness between BIC or BIPI and Roxane or that BIC or BIPI pervasively controlled Roxane. In addition, BIC disputes that the Government's additional facts are material to its motion for summary judgment or the Government's claims against it as they relate solely to BIPI.

69. Because BIPI had experience in the respiratory product market from its sales of Atrovent, as Roxane prepared to launch its generic product, BIPI shared information and expertise on a high-level about the respiratory drug market and current market conditions. No one from BIPI was involved in marketing details or price setting for Roxane's ipratropium bromide. (Tab 1, 1/27/05 Berkle Dep. 28, 38, 72-73)

United States' Response: Disputed. Further answering, *see supra* United States' Responses to Paragraphs 7, 53 and 68.

BIC and BIPI's Reply: The Government's response does not create a disputed issue of fact material to BIC and BIPI's motion for summary judgment. BIC and BIPI incorporate their Replies to ¶¶ 7, 53, and 68.

70. In 2000, Roxane sought to change the AWP on one of its multi-source products, furosemide, due to customer complaints that it was out of line with the AWP's for that drug in the rest of the market. (Tab 29 5/9/07 Waterer Dep. 75-76) Roxane's marketing and sales teams compiled supporting documentation for the AWP change, and the marketing department developed a price change recommendation for Mr. Russillo's review. (Tab 17, 11/30/05 Paoletti Dep. 141-145; Tab 29, 5/9/07 Waterer Dep. 201-202)

United States' Response: Undisputed, except that when Mr. Russillo requested supporting documentation for the furosemide price change, he advised Mr. Sykora that "[t]o get the approval we need from Connecticut," we "need some 'hard' info" about competitors' AWP's. (BIC/BIPI Fauci Exhibit 95) Mr. Russillo testified that "Ridgefield, Connecticut, to me meant BIPI." (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 36:5 - 36:22) Other emails sent by Ms. Waterer describe Mr. Russillo as willing to "champion" or "support" the furosemide AWP increase, indicating that approval from Mr. Russillo's superior at Boehringer Ingelheim was required. (BIC/BIPI Fauci Exhibit 94)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing

parties.”). The Government’s additional facts do not controvert BIC and BIPI’s statement of fact and do not create a disputed issue of fact material to their motion for summary judgment.

BIC and BIPI do not dispute that in the email BIC/BIPI Fauci Exhibit 95 Mr. Russillo wrote “[t]o get the approval we need from Conn. though we need some ‘hard’ info.” However, BIC and BIPI dispute that in this email that Mr. Russillo’s reference to Connecticut was meant to refer to BIPI. In his testimony, when discussing this email, Mr. Russillo explains that he did not need approval from Boehringer Ingelheim in Connecticut unless he felt that he needed to review circumstances with Werner Gerstenberg who was physically located there. (Tab 106, 1/8/09 Russillo Dep. 178-79) Mr. Gerstenberg was both the President and CEO of BIC and the President and COO of Roxane in 2000 and Mr. Russillo testified that, if he had consulted with Mr. Gerstenberg regarding the furosemide AWP change, Mr. Gerstenberg “would have been acting as the president of Roxane.” (BIC/BIPI SOF at ¶ 30 and US Resp to BIC/BIPI SOF at ¶ 30; Tab 106, 1/8/09 Russillo Dep. 175) While Mr. Russillo did testify that “Ridgefield, Connecticut, to me meant BIPI,” it was in a completely different context regarding a wholly unrelated document, Exhibit 2 from Mr. Russillo’s 1/8/2009 Deposition testimony, which was a news release put out by BIPI. (Tab 106, 1/8/09 Russillo Dep. 35-36; *see also* Tab 128, Russillo Ex. 2, 1/28/99 BIPI Press Release) BIC and BIPI also dispute that “approval from Mr. Russillo’s superior at Boehringer Ingelheim was required” for the furosemide AWP change as that fact is not supported by the Government’s proffered evidence, BIC/BIPI Fauci Exhibit 94. In BIC/BIPI Fauci Exhibit 94, Ms. Waterer merely states that “Tom is prepared to take furosemide up the line.” Mr. Russillo explains in his testimony that such reference to “up the line” would be to Werner Gerstenberg, who “would have been acting as the president of Roxane” and that “up the line” would not include anyone else

other than Werner Gerstenberg. (Tab 106, 1/8/09 Russillo Dep. 174-75) BIC and BIPI also incorporate their Reply to ¶ 61.

71. Mr. Russillo approved the marketing department's recommendation to increase furosemide's AWP. While Mr. Russillo did not believe he sought further approval for the furosemide price increase, he explained that if he had, he would have discussed the price change with Werner Gerstenberg, in his role as President and COO of Roxane. (Tab 20, Russillo Dep. 167-168, 174-75, 178-179, 191-192)

United States' Response: Disputed. As noted *supra*, Mr. Russillo testified that he reported to Mr. Gerstenberg "in his role as president and CEO of BIC." (BIC/BIPI Fauci Exhibit 10 (1/8/2009 Russillo Dep.) at 29:8 - 30:10, 204:1 - 204:7, 205:19 - 207:2) The evidence supports the conclusion that Mr. Russillo reported to Mr. Gerstenberg as CEO of BIC for several reasons. First, Mr. Russillo testified that he reported to Mr. Gerstenberg both when Mr. Russillo was acting as the Chief Operating Officer at Ben Venue Labs and when he was supervising Roxane's multi-source marketing. (*Id.*) Mr. Russillo did so even though there is no evidence that Mr. Gerstenberg was an officer of Ben Venue Labs. Second, Mr. Russillo continued to report to Mr. Gerstenberg through 2003, *after* Mr. Gerstenberg had stepped down as President of Roxane, but when Mr. Gerstenberg was still serving as President of BIC. (*Id.*) Third, Mr. Russillo testified that he reported to Martin Carroll as President of BIC after Mr. Carroll replaced Mr. Gerstenberg in that role, even though Mr. Carroll was not an officer at Roxane. (*Id.*; *see also* BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.) at 31:11 - 32:10)

BIC and BIPI's Reply: The Government's response does not create a disputed issue of fact material to BIC and BIPI's motion for summary judgment. BIC and BIPI dispute that Mr. Russillo reported to or sought approval from Mr. Gerstenberg "in his role as president and CEO of BIC" in relation to Roxane's decision to change the AWP for furosemide or with respect to Roxane pricing or marketing decisions, generally. As discussed in detail above, Mr. Gerstenberg was both the President and CEO of BIC and the President and COO of Roxane in 2000 and Mr. Russillo testified that, if he had consulted with Mr. Gerstenberg regarding the furosemide AWP change, Mr. Gerstenberg "would have been acting as the president of Roxane." (BIC and BIPI's Reply to SOF ¶ 62; BIC/BIPI SOF at ¶ 30 and US Resp. BIC/BIPI SOF at ¶ 30; Tab 106, 1/8/09 Russillo Dep. 175) Indeed, when asked who he reported to "regarding marketing decisions for Roxane's multisource products," Mr. Russillo stated that "Werner Gerstenberg was the president of Roxane

Laboratories. As such, I had an obligation to keep him informed as to what was going on.” (Tab 106, 1/8/09 Russillo Dep. 28)

The Government’s reference to Mr. Russillo’s later testimony where he responded “yes” to more general questions regarding whether he reported to Mr. Gerstenberg “in his role as president and CEO of BIC” and whether he was directed by Mr. Gerstenberg in that role to take over management of Roxane’s multisource business does not contradict his testimony that, to the extent he was consulted regarding the furosemide decision or Roxane marketing decisions, Mr. Gerstenberg was acting in his Roxane role. As the Government recognizes in its Response to this statement of fact, at the time Mr. Russillo became the Head of Roxane’s Multisource products, Mr. Russillo was the President and COO of a separate BIC subsidiary, Ben Venue Laboratories, and in that role he would have reported to Mr. Gerstenberg as the President and CEO of BIC. (*See Id.* at 43-44; Tab 32, Jan. 1998 Organization Chart; Tab 33, Jan. 2000 Organization Chart) In addition, it makes sense that Mr. Gerstenberg was acting in his role as President and CEO of BIC when he directed the President of another BIC subsidiary to take on a high-level role at a different subsidiary. Further, Mr. Russillo remained President and COO of Ben Venue until he left the company and therefore would have continued to report to Mr. Gerstenberg after he stepped down as President and COO of Roxane, and then Mr. Carroll in their capacities as the President and CEO of BIC. And even in his Roxane role, there may have been higher level strategy or organizational issues that Mr. Russillo discussed with Mr. Gerstenberg and Mr. Carroll in their role at the parent company. Thus, all of the points raised by the Government merely reflect that both Mr. Russillo and Mr. Gerstenberg both wore more than one “hat” and thus had different reporting relationships in their different capacities.

Moreover, even if Mr. Russillo in his role as Head of Roxane Multisource reported to Mr. Gerstenberg after 2003 and Mr. Carroll after that in their capacities as the President and CEO of

BIC, this is immaterial to BIC and BIPI's motion for summary judgment and the Government's claims against them as the Government points to no evidence that either Mr. Gerstenberg or Mr. Carroll were involved in any AWP or other pricing or marketing decision for any Subject drug during that timeframe. And in particular, there is no dispute that the furosemide price change occurred while Mr. Gerstenberg was serving as President and COO of Roxane. In addition, BIPI disputes that the Government's alleged statements are material to its motion for summary judgment or the Government's claims against it as they related solely to BIC.

(b) Marketing of Brand and Branded Generic Products

72. Until the 2000-2001 timeframe, Roxane sold a small line of brand and branded generic drugs in addition to its main line of multi-source generic drugs. These drugs included HIV and palliative care/pain products. (Tab 7, 6/25/02 Feldman Dep. 174; Tab 2, 10/31/08 Berkle Dep. 30-31; Tab 21, 5/21/08 Shaffer Dep. 54-55; Tab 84, RLI-ORG 00000083 (1999 Roxane Sales Org. Chart))

United States' Response: The United States disputes that Roxane's brand and branded generic drugs constituted a "small line" of products. According to a Roxane "Position Paper" from 1999, Roxane's "largest seller" at that time was Viramune®, an HIV/AIDS drug assigned to Roxane by BIPI, which accounted for \$106 million of Roxane's expected \$412 million in third-party net sales for 1999. (BIC/BIPI Fauci Exhibit 60 at BOEH02601796) The Position Paper described Roxane's "branded generics" in the pain/palliative care area as "important contributors to its sales and profits." (*Id.*) The Position Paper specifically noted that Oramorph SR, Roxicodone and Roxanol (all branded generic products and all Subject Drugs) collectively produced sales of \$40 million in 1999. (*Id.*)

BIC and BIPI's Reply: Other than disputing BIC and BIPI's characterization of its brand and branded products as a "small line," the Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). The Government's additional facts do not controvert BIC and BIPI's statement of fact and do not create a disputed issue of fact material to their motion for summary judgment.

The Government's dispute that Viramune was Roxane's "largest seller" in 1999 is immaterial, and does not contradict the substance of the statement of fact that Roxane's brand and branded generic line was small relative to its multisource line. Even if Viramune, Roxicodone, Oramorph and Roxanol accounted for \$146 million of Roxane's \$412 million of sales, the vast majority of sales dollars are still attributable to Roxane's multisource line. Additionally, Viramune, Oramorph SR, Roxicodone, and Roxanol are only a few products out of the roughly 400-500 NDCs that have historically been in the Roxane product line. (Tab 93, 5/30/07 DeCapua Dep. 167) Thus, Roxane's line of brand and branded generic drugs was small relative to the number of its multisource products.

In addition, BIC and BIPI dispute that the Government's additional fact is material to the Government's claims against them as it relates to a drug, Viramune, that is not one of the Subject Drugs at issue in this case.

73. Branded generic drugs are generic drugs that have been given proprietary names beyond the chemical formulation (such as Roxicodone, Roxicet or Roxanol) and are marketed to physicians in the same manner as brand products. (Tab 2, 10/31/08 Berkle Dep. 31; Tab 3, 12/12/08 Carr Hall Dep. 74-75)

United States' Response: The United States does not dispute that Roxane regarded its branded generic products as drugs with proprietary names, and that Roxane marketed those drugs according to a branded marketing strategy.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). BIC and BIPI also incorporate Roxane's Responses to ¶ 7 of the US' SOF regarding Roxane, which explains that Roxane employees defined the term "branded generic" in different ways and that some Roxane employees considered Roxicodone 15 and 30mg tablets to be branded

products as opposed to “branded generics.” The distinction, however, is immaterial to BIC and BIPI’s motion for summary judgment; rather it is only material that Roxane distinguished internally for marketing purposes between what it called its “multisource” products and the “branded/branded generic” products that were part of the palliative care line marketed to physicians by a physicians’ sales force. (*See* Roxane Resp. to US Roxane SOF at ¶ 7)

74. Roxicodone, Oramorph SR, and Roxanol -- three of the drugs at issue in this case -- were part of Roxane’s branded generic palliative care line. (*See* United States’ First Amended Complaint at 158; Tab 21, 5/21/08 Shaffer Dep. 55)

United States’ Response: Undisputed. *See supra* United States’ Response to Paragraph 72.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI incorporate their Reply to ¶ 72. BIC and BIPI also note that this statement of fact should have stated that Roxicodone, Oramorph SR and Roxanol are part of Roxane’s brand and branded generic palliative care line.

75. Roxane had its own marketing staff dedicated to promoting its brand and branded generic products that was separate from its multi-source marketing team. The marketing staff reported to Gary Ellexson, Executive Director of Marketing RLI Brands. Mr. Ellexson reported to Ed Tupa, Vice President of Marketing at Roxane, until he left the company in October 1998. The marketing staff product managers were responsible for launching new products and Ed Tupa was involved in developing pricing for the brand/branded generic products. (Tab 29, 5/10/07 Waterer Dep. 254-56; Tab 5, 7/25/07 Ciarelli 33-34; Tab 4, 6/26/02 Ciarelli Dep. 30-31, 98; Tab 29, 5/10/07 Waterer Dep. 304; Tab 25, 10/18/05 Via Dep. 42-44, 50; Tab 21, 5/21/08 Shaffer Dep. 50; Tab 85, 5/21/08 Shaffer Dep. Ex. 10 (Oramorph SR Price Increase))

United States’ Response: The United States does not dispute that Roxane employed a palliative cares field sales force or that Mr. Tupa and Mr. Ellexson had responsibility for promoting Roxane’s branded generic drugs. The United States disputes this paragraph to the extent it implies that BIC and/or BIPI were not actively involved in the conduct for which the United States is seeking damages. As noted *supra* in the United States’ Response to Paragraph 51, BIPI employees’

involvement in the approval of marketing strategies and pricing for Roxane's branded generic products was both formal and pervasive. Roxane and BIPI shared a common "Pricing Policy and Procedure" for BIPI's products and Roxane's branded generic products, which required approval of a proposed AWP first by a joint Roxane/BIPI pricing committee and then by the "Executive Vice President, Ethical Pharmaceuticals" (Mr. Berkle) and the "President and CEO, Boehringer Ingelheim Corporation" (Mr. Gerstenberg). (BIC/BIPI Fauci Exhibit 78; BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.) at 214:22 - 215:19) No fewer than five BIPI employees were involved in the decision to approve WAC and AWP pricing for Roxane's August 2000 launch of Roxicodone. (*See supra* United States' Response to Paragraph 51)

Moreover, even though Roxane had a palliative care sales force, the National Account Managers in the Trade Relations Group also had responsibility for promoting branded generic products. (*See, e.g.*, BIC/BIPI Fauci Exhibit 101 (11/4/2005 Gordon Dep.) at 55:21 - 57:6; BIC/BIPI Fauci Exhibit 102 (10/18/2005 Via Dep.) at 43:22 - 44:3; BIC/BIPI Fauci Exhibit 103 (12/12/2008 Carr-Hall Dep.) at 63:13 - 64:8) Robert Sykora, who was a BIPI employee with responsibility for promoting Roxane and BIPI products, prepared a series of slides to present to Roxane's palliative care sales force in anticipation of the launch of Roxane's 15/30 mg Roxicodone tablets. (BIC/BIPI Fauci Exhibit 36 (11/2/2005 Sykora Dep.) at 22:20 - 23:5; BIC/BIPI Fauci Exhibit 12 (12/4/2008 Sykora Dep.) at 133:7 - 135:13. One slide noted that Roxicodone 15 mg and 30 mg was typically more profitable for pharmacies to dispense. (BIC/BIPI Fauci Exhibit 104, at BOEH01301726)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). To the extent the Government's response is anything other than an unqualified admission, BIC and BIPI object to the Government's response because it is not clear what material facts, if any, it is disputing. The Government's additional alleged facts do not contradict this statement of fact and do not create a disputed issue of fact material to BIC and BIPI's motion for summary judgment.

BIC and BIPI dispute that "BIPI employees' involvement in the approval of marketing strategies for Roxane's branded generic products was both formal and pervasive." The Government's proffered evidence does not support this alleged fact. First, the "Pricing Policy and Procedure" document was a non-final, draft policy circulated to several employees for comment.

(BIC/BIPI Fauci Ex. 78, 5/3/01 Email attaching Pricing Policy and Procedure draft at 1 (“All, Please review the attached ‘Draft’ Pricing Policy and Procedure and provide me any changes you deem appropriate.”)) The Government points to no credible evidence this draft policy was ever implemented or that Roxane set any AWP for a Subject Drug pursuant to these proposed practices. Indeed, Mr. Berkle testified that he only recalled the policy being implemented with respect to BIPI products, not Roxane’s branded and branded generic products. (Tab 90, 10/31/08 Berkle Dep. 225-26) Further, the Government admits the draft “Pricing Policy and Procedure” document only relates to Roxane’s branded and branded generic products, namely Roxicodone, Oramorph SR, and Roxanol. Since Roxane divested these three products in September 2001 and the draft document is dated May 2001, the policy would have only been in place for a few months, if it was implemented at all. (*Id.* at 215-16, 225-26; BIC/BIPI SOF at ¶ 81) BIC and BIPI also incorporate their Reply to ¶ 51.

Additionally, although a handful of BIPI employees may have commented on the launch prices for Roxicodone 15mg and 30mg tablets, Roxane employees and consultants wrote and developed the Roxicodone launch plan, not BIPI or BIC employees. (Tab 126, Duy Ex. 32, 8/1/00 Email re Roxane Marketing Resources; BIC/BIPI Fauci Ex. 20, 12/16/08 Duy Dep. 173-74; BIC/BIPI Fauci Ex. 15, 10/31/08 Berkle Dep. 234; BIC/BIPI Fauci Ex. 80, 8/12/00 Email attaching Roxicodone 15/30mg Launch Plan; BIC/BIPI SOF at ¶ 79) Roxane had its own marketing staff dedicated to promoting and developing the brand strategy for its brand and branded generic products (BIC/BIPI SOF at ¶ 75), and BIPI employees only provided strategic input based on their experience marketing branded drugs. (Tab 90, 10/31/08 Berkle Dep. 234) Further, the launch prices and plan were approved as drafted and proposed by Roxane’s marketing group and employees. (*See* BIC/BIPI Fauci Ex. 86, 8/22/00 Memo re Recommended Pricing for Roxicodone IR; BIC/BIPI

Fauci Ex. 87, 8/24/00 Email re Roxicodone WAC AWP proposal; BIC/BIPI Fauci Ex. 80, 8/12/00 Email attaching Roxicodone 15/30mg Launch Plan at SHAFFER 001516) In addition, the BIPI personnel that commented on the Roxicodone proposal held high level supervisory roles with respect to Roxane's brand and branded generic products or had positions in a consolidated or shared service department, like contract pricing and administration. (BIC/BIPI Fauci Ex. 18, 10/23/98 Employee Bulletin re organizational changes at 3-4 (King, Leonetti, and Ciarelli given or held supervisory positions); Tab 91, 6/26/02 Ciarelli Dep. 16-17 (Ciarelli and Ferrara, who worked for Ciarelli, responsible for shared contracts pricing administration.)) Thus, to the extent they approved or commented on the launch prices for Roxicodone, they were acting on behalf of Roxane, not BIPI. (BIC/BIPI SOF at ¶ 93) BIC and BIPI also incorporate their Reply to ¶ 51.

Thus, BIC and BIPI dispute that the Government's alleged facts related to (BIC/BIPI SOF at ¶ 93) the draft pricing proposal and the launch of Roxicodone are material to their motion for summary judgment or the Government's direct liability or veil-piercing claims against them as they do not demonstrate that BIC or BIPI were involved in setting or reporting AWP's for any Subject Drugs, nor do they demonstrate as lack of separateness between Roxane and BIC or BIPI or that BIC or BIPI pervasively controlled Roxane.

Second, BIC and BIPI do not dispute that Ms. Gordon testified that she was involved in the launch of Roxicodone 15 and 30mg tablets in 2000, but dispute that this is material to BIC and BIPI's motion for summary judgment. In addition, BIC and BIPI note that Mr. Via's testimony only supports that he was involved with Roxane's brand and branded generic products in his position as a product manager in the brand and branded generic marketing department, not while he was a National Account Manager. (BIC/BIPI Fauci Ex. 102, 10/18/05 Via Dep. 43-44) BIC and BIPI do not dispute that Mr. Sykora had responsibilities for both Roxane and BIPI products for a certain

period of time. However, Mr. Sykora and Roxane's National Account Managers primarily focused on Roxane products and only worked with BIPI products on a very limited basis. (*See* BIC and BIPI's Reply to ¶ 63; Tab 96, 11/4/05 Gordon Dep. 35; Tab 109, 12/4/08 Sykora Dep. 50-52) Thus, BIC and BIPI dispute that this fact is material to their motion for summary judgment. BIC and BIPI do not dispute that Mr. Sykora presented a series of slides to Roxane's palliative care sales force in connection with the launch of Roxicodone 15/30mg, but BIC and BIPI do dispute that Mr. Sykora prepared these slides. An outside advertising agency prepared the referenced slides and Mr. Sykora only presented them to the sales force. (Tab 109, 12/4/08 Sykora Dep. 137-38) BIC and BIPI also dispute that Mr. Sykora was a BIPI employee at the time of the presentation as this fact is not supported by the Government's proffered evidence. Mr. Sykora testified only that he worked generally for "Boehringer Ingelheim," not that he worked for BIPI. Roxane Laboratories was a subsidiary of Boehringer Ingelheim Corporation and Mr. Sykora later clarified that he considered Roxane his employer. (*Id.* at 50) In addition, the record shows that in fact Mr. Sykora was a Roxane employee until December 2000. (Tab 123, 11/30/00 Letter from Judy Orinski to Robert Sykora, RLI-AWP-00160361-362) Thus, this fact is immaterial to BIC and BIPI's motion for summary judgment. Further, BIC and BIPI do not dispute that one slide of Mr. Sykora's presentation stated what the Government describes in the last sentence of its Response. However, as Mr. Sykora explained, the purpose of his presentation was to "educate the salesforce" that if they worked to get physicians to write prescriptions for 15mg and 30mg Roxicodone, the pharmacy would not have an incentive to substitute three or six generic 5mg tablets for the 15mg or 30mg prescription; the sales force had previously complained that the Roxicodone 5mg prescriptions they generated at physicians' offices were being substituted at the pharmacies with another generic competitor. (Tab 109, 12/4/08 Sykora Dep. 173-77; Tab 92, 7/25/07 Ciarelli Dep. 68-71) The presentation

regarding reimbursement was thus designed to “allay [the sales forces’] fear” of substitution, not to have the sales force “educate the pharmacies on it.” (Tab 109, 12/4/08 Sykora Dep. 174-75) Indeed, Mr. Sykora testified that the sales force did not have “enough knowledge or expertise in reimbursement to present something as complicated as what I’m seeing here to a pharmacy and talk about reimbursement.” (*Id.*) Moreover, while the referenced slide states that it would “typically” be more profitable to dispense Roxane’s product, the more detailed pricing proposals specifically state that Roxane’s Roxicodone was priced to be below but “in line with existing Roxicodone 5mg WAC prices,” “reasonably comparable to competitive prices” and to provide a “similar” profit to 5mg competitors. (BIC/BIPI Fauci Ex. 80, 8/12/00 Email attaching Roxicodone 15/30mg Launch Plan at SHAFFER 001516; BIC/BIPI Fauci Ex. 86, 8/22/00 Boehringer Memo re Recommended Pricing for Roxicodone IR at BOEH00242612-13) Indeed, the documents show that a wide range of AWP and WACs existed for 5mg competitors and that Roxane’s 15mg and 30mg proposed AWP and WACs fell close to the middle of that range. (*Id.*)

76. Roxane employees were responsible for providing its brand/branded generic prices to the pricing compendia. (*See, e.g.*, Tab 78, 5/10/07 Waterer Dep. Ex. 35 (Red Book 14084-85); Tab 77, 5/10/07 Waterer Dep. Ex. 34 (Red Book 14071-83); *see also* pricing communications listed in ¶ 63)

United States’ Response: Disputed. Gregg Ciarelli testified that from 1997 through 2000, he had “ongoing responsibility” for reporting prices to First Data Bank for Roxane’s branded products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.) at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21) Mr. Ciarelli was employed and paid by BIPI for his entire tenure with Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.) at 9:17 - 10:11, 50:6 - 50:13)

BIC and BIPI’s Reply: The Government’s response does not create a disputed issue of fact material to BIC and BIPI’s motion for summary judgment. BIC and BIPI dispute that “BIPI personnel were responsible for reporting AWP to the pricing compendia for Roxane’s branded and branded generic products” as this fact is not supported by the Government’s proffered evidence, BIC/BIPI Fauci Exhibit 52. Mr. Ciarelli does not testify that BIPI personnel reported AWP to the

pricing compendia for Roxane's branded and branded generic products. Rather, Mr. Ciarelli testifies that "one of the people in Roxane who reported to me, John Powers, reported those prices." (Tab 92, 7/25/07 Ciarelli Dep. 24) Moreover, to the extent that Mr. Ciarelli may have had any involvement supervising the reporting of prices for Roxane's brand and branded generic products during a limited timeframe, it is immaterial to BIC and BIPI's motion for summary judgment and the Government's direct liability claims against them as Mr. Ciarelli was acting on behalf of Roxane pursuant to the role and responsibilities he had been given for Roxane's brand and branded generic products, and therefore his conduct cannot be imputed to BIPI. (*Id.* at 21-23; Tab 63, 10/23/98 Reorganization Memo at 4; BIC/BIPI SOF at ¶ 93). BIC and BIPI also incorporate their Reply to SOF ¶ 51. Moreover, Mr. Ciarelli's role with regard to Roxane's branded generic products is immaterial to BIC and BIPI's motion for summary judgment and the Government's veil-piercing claims against them because it is common for affiliated companies to have overlapping managers (BIC/BIPI SOF at ¶ 90), and the evidence does not suggest that Mr. Ciarelli exercised pervasive control over any part of Roxane's business. In addition, BIC disputes that this additional fact is relevant to its motion for summary judgment or the Government's claims against it because it relates solely to BIPI.

77. Roxane also had its own field sales force responsible for promoting its palliative care and HIV products, mainly to physicians, and they reported to Jerry Hart, as Director of RLI Brand Sales. (Tab 22, 8/5/08 Shaffer Dep. 363; Tab 86, RLI-ORG00000082 (1998 Roxane Sales Department Organization Chart)) In 1999, the palliative care and HIV divisions of the RLI Brand sales group split; the HIV group continued to report to Mr. Hart, and the palliative care group began reporting to Mark Shaffer as Director of Sales for Palliative Care. (Tab 21, 5/21/08 Shaffer Dep. 54; Tab 84, RLI-ORG00000083 (1999 Roxane Sales Department Organization Chart)) The HIV sales force had roughly 35-50 members, and the palliative care sales force had roughly 50 members. (Tab 25, 10/18/05 Via Dep. 87)

United States' Response: Undisputed, except the palliative care sales force was not exclusively responsible for promoting these products. (*See supra* United States' Response to Paragraph 75)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement

required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI incorporate their Reply to ¶ 75.

78. In late 1998, organizational changes were made to leverage the expertise and experience in marketing brand name products of several BIPI-based employees for the benefit of Roxane’s brand and branded generic products, and certain Roxane employees in marketing and sales for branded generics began to report functionally to designated people at BIPI. (Tab 2, 10/31/08 Berkle Dep. 59-60). Specifically,

- Gary Ellexson, Director of Roxane’s Branded and Specialty Marketing, began reporting to Greg Fulton, who became head of BIPI/RLI Branded Marketing. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161739 (10/23/98 Reorganization Memo); Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Roxane Laboratories, Inc. Budget 1999 Organizational Chart) (Budget 1999 Org. Chart)) Roxane’s Branded Marketing staff continued to report to Ellexson. (*Id.*)
- Jerry Hart, Director of Roxane Sales, began reporting to Jim King, who became head of BPI/RLI Branded Sales. Roxane’s field sales force continued to report to Hart. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161739 (10/23/98 Reorg. Memo); Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Budget 1999 Org. Chart))
- BIPI and RLI Contract Administration continued to have departments at both BIPI and Roxane, but management was streamlined. (Tab 63, 10/31/08 Berkle Dep.; Ex. 27 at RLI-AWP-00161740 (10/23/98 Reorganization Memo)) John Powers, Roxane’s Director of Contracts, began reporting to Gregg Ciarelli, who became head of Contracting and Marketing Controlling. Powers, was responsible for day-to-day management of the groups in both locations. (*Id.*; Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Budget 1999 Org. Chart))

United States’ Response: The United States does not dispute that organizational changes in the Business Unit were made in 1998 or that, in accord with such changes, Roxane employees “functionally” reported to employees at BIPI. The United States disputes this paragraph to the extent it implies that Roxane employees did not report to their BIPI counterparts prior to 1998. The Employee Bulletin announcing the 1998 organizational changes made clear that such changes built on steps taken “in the past two years to increase the level of Business Unit collaboration and focus across organization.” (BIC/BIPI Fauci Exhibit 18; *see generally* United States’ Responses to Paragraphs 7 and 53)

Further answering, the United States does not dispute that Mr. Fulton, Mr. King and Mr. Ciarelli supervised employees at Roxane. The United States also does not dispute that Mr. Powers reported to Mr. Ciarelli at BIPI, and that Mr. Powers managed the contracts functions for both Roxane and BIPI. The United States disputes, however, that Roxane and BIPI continued to have separate contracts departments. Beginning in at least 1998, the Contracts Functions was

located at BIC and BIPI's headquarters in Connecticut. (BIC/BIPI Fauci Exhibit 56 (11/9/2004 Paoletti Dep.) at 90:15 - 92:6) Moreover, Mr. Powers testified that beginning in 1996 "decisions were made that the Roxane business and the Boehringer business should get closer together in terms of management, that the two companies shouldn't be run as two separate entities any longer." (BIC/BIPI Fauci Exhibit 47 (2/4/2003 Powers Dep.) at 40:14 - 42:1)

BIC and BIPI's Reply: Other than disputing the date on which certain Roxane employees began reporting functionally to BIPI employees and the date Roxane and BIPI consolidated contracts departments, the Government does not dispute the substance of BIC and BIPI's statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

The Government's alleged fact that Roxane employees responsible for brand and branded generic products began reporting functionally to BIPI counterparts earlier than 1998 is unsupported by the Government's proffered evidence. The Employee Bulletin selectively quoted by the Government does not imply whatsoever that Roxane employees reported to BIPI employees prior to 1998. Indeed, language omitted by the Government explains that the formation of two committees was the foundation for the 1998 organizational changes, not that Roxane employees reported to BIPI employees prior to 1998:

As we are all aware, we have taken several steps in the past two years to increase the level of Business Unit collaboration and focus across organizations (e.g., Business Unit Operating Committee, Ethical Pharmaceutical Committee). The changes I will describe in this announcement build on this foundation.

(BIC/BIPI Fauci Ex. 18, 10/23/98 Employee Bulletin re organizational changes at 2) BIC and BIPI also incorporate their Replies to ¶¶ 7, 51, 53.

Further, BIC and BIPI do not dispute that the Roxane contracts administration department was eventually combined with the BIPI contracts department into a single unit that provided centralized contract administration services to both Roxane and BIPI and that Roxane was charged and paid for these services. (BIC/BIPI SOF at ¶ 49) As Mr. Berkle explained, “this happened really from the administrative perspective . . . the actual establishment of pricing or contracting was done by individuals within the Roxane business entity, but the processing of the administration . . . were done by a central unit” (Tab 90, 10/31/08 Berkle Dep. 60-61) BIC and BIPI dispute the Government’s alleged fact that the departments were consolidated “[b]eginning in at least 1998.” The Government’s proffered evidence does not indicate the date the departments were consolidated, and other testimony reveals the departments consolidated operations in or around January 2001. (Tab 100, 5/31/07 Marsh Dep. 118) Finally, BIC and BIPI dispute the Government’s selective quoting from Mr. Powers’ deposition. Mr. Powers was speaking in the context of the contracts department, not the company as a whole. Indeed, the contracts departments of the two companies were later consolidated for efficiency purposes. (BIC/BIPI Fauci Ex. 47, 2/4/03 Powers Dep. 40-42)

79. Fulton, King, and Ciarelli provided an additional line-of-sight in the organization, but Roxane employees continued to handle the day-to-day operations of its brand and branded generic lines, including sales and marketing. (Tab 2, 10/31/08 Berkle Dep. 59-60 (“Those people within the Roxane business entity did report functionally to designated people within the BIPI organization, but the day-to-day operations were still conducted by Roxane people.”); *Id.* 191- 192 (“it made sense to combine . . . at certain levels the reporting relationship to . . . allow Roxane to benefit from the expertise within BIPI . . . I emphasize that the day-to-day operations were conducted for the Roxane . . . branded generic products within the Roxane structure.”))

United States’ Response: The United States does not dispute that Mr. Fulton, Mr. King and Mr. Ciarelli supervised Roxane employees. The United States disputes any implication that Mr. Fulton, Mr. King and Mr. Ciarelli were not involved in “day-to-day operations” at Roxane. Further answering, Mr. King and Mr. Ciarelli were on the pricing committee and exercised regular and formal authority in approving Roxane’s prices, including AWP. (*See supra* United States’ Response to Paragraph 53) Moreover, Mr. Ciarelli had “ongoing” responsibility for reporting AWP for Roxane’s branded generic products. (BIC/BIPI Fauci Exhibit 52 (7/25/2007 Ciarelli Dep.) at 22:10 - 24:10, 28:17 - 29:4, 49:17 - 49:21)

BIC and BIPI's Reply: The Government's response does not create a disputed issue of fact material to BIC and BIPI's motion for summary judgment. BIC and BIPI dispute the Government's alleged fact that Mr. Fulton, Mr. King's and Mr. Ciarelli were involved in Roxane's day-to-day operations as this alleged fact is not supported by the Government's proffered evidence. BIC and BIPI dispute that Mr. King and Mr. Ciarelli's roles on the Pricing and Terms Committee constituted "regular and formal authority in approving Roxane's prices, including AWP's." (*See* BIC and BIPI's Reply to ¶ 53)

BIC and BIPI do not dispute that Mr. Ciarelli testified as indicated, but his testimony makes clear that neither he nor any BIPI personnel reported AWP's to the pricing compendia for Roxane's branded and branded generic products. Rather, Mr. Ciarelli testified that "one of the people in Roxane who reported to me, John Powers, reported those prices." (Tab 92, 7/25/07 Ciarelli Dep. 24) Moreover, to the extent that Mr. Ciarelli may have had any involvement in reporting prices for Roxane's brand and branded generic products, it is immaterial to BIC and BIPI's motion for summary judgment and the Government's direct liability claims against them because Mr. Ciarelli was acting on behalf of Roxane pursuant to the role and responsibilities he had been given for Roxane's brand and branded generic products, and therefore his conduct cannot be imputed to BIPI. (*Id.* at 21-23; Tab 63, 10/23/98 Reorganization Memo at RLI-AWP-00161740) BIC and BIPI also incorporate their Reply to ¶ 51. Moreover, Mr. Ciarelli's role with regard to Roxane's branded generic products is immaterial to BIC and BIPI's motion for summary judgment and the Government's veil-piercing claims against them because it is common for affiliated companies to have overlapping managers, and the evidence does not suggest that Mr. Ciarelli exercised pervasive control over any part of Roxane's business. In addition, BIC disputes that this additional fact is

relevant to its motion for summary judgment or the Government's claims against it because it relates solely to BIPI.

80. In 2000, the decision was made to divest Roxane's palliative care and HIV line so that it could focus its business on generic products. Marketing operations for the palliative care drugs began to wind down, and at the end of 2000, the sales force dissolved and Roxane no longer had sales people promoting those products. (Tab 21, 5/21/08 Shaffer Dep. 225-226, 355- 356; Tab 10, King Dep. 197) Roxane also stopped promoting Viramune, a brand name HIV drug that it licensed from BIPI. Viramune was transferred back to BIPI in 2001. (Tab 42, BOEH04600348-52, BOEH04600353-62 (Roxane Unanimous Consents); Tab 15, McIntyre Dep. 158-159)

United States' Response: Undisputed. Further answering, this decision was first made at a BIC/BIPI Board meeting. (*See supra* United States Response to Paragraph 27)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties."). BIC and BIPI dispute that the decision to divest the pain/palliative care products was made in May 2000, at a joint meeting of the Boards of Directors of BIC and BIPI. Rather, the minutes of the joint meeting indicate that the divestiture was merely a topic of discussion. (BIC/BIPI Fauci Ex. 8, 5/15/00 BIC/BIPI Board of Directors Meeting Minutes at BICJURIS0179-180) The minutes reflect that "U.S. management, following discussion with the board, have approved a restructuring," and that "[a]lternatives will be considered regarding selling the pain/palliative care business," but no board resolution was made adopting any decisions regarding the divestiture. (*Id.*) Additionally, the minutes point out that the decision to implement the restructuring was "deferred pending further developments in the lawsuit regarding MARINOL®." (*Id.* at BICJURIS0180) This sort of high-level reporting is within the normal range of information on which a parent company would be updated. (Tab 98, 5/19/09 Macey Dep. 131 (noting that it is "standard practice for a parent corporation to monitor and oversee its subsidiaries' operations" and

“to set high level policy and strategy at a subsidiary.”)) Ultimately, however, it was the Roxane Board of Directors, not BIC’s Board, that approved the sale by entering unanimous written consents, approving the sale to Elan Pharma International, Limited. (Tab 42, Roxane Unanimous Consents at BOEH04600226-247, BOEH04600369)

81. On September 28, 2001, Roxane divested Roxicodone, Oramorph, Roxanol, and several other palliative care drugs to Elan Pharmaceuticals pursuant to an Asset Purchase Agreement. (Tab 53, BOEH01046045-6092 (Elan Asset Purchase Agreement); (Tab 42, BOEH04600369-74 (Roxane Unanimous Consents)) Roxane booked a \$200 million payment from Elan for the divested drugs. (Tab 48, BOEH02675446-72 at 50-52, 58 (Commentary To The Financial Statements For Year End 12/31/01))

United States’ Response: Undisputed. Further answering, this decision was first made at a BIC/BIPI Board meeting. (*See supra* United States Response to Paragraph 27)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI dispute that the decision to divest the pain/palliative care products was made in May 2000, at a joint meeting of the Boards of Directors of BIC and BIPI. Rather, the minutes of the joint meeting indicate that the divestiture was merely a topic of discussion. (BIC/BIPI Fauci Ex. 8, 5/15/00 BIC/BIPI Board of Directors Meeting Minutes at BICJURIS0179-180) The minutes reflect that “U.S. management, following discussion with the board, have approved a restructuring,” and that “[a]lternatives will be considered regarding selling the pain/palliative care business,” but no board resolution was made adopting any decisions regarding the divestiture. (*Id.*) Additionally, the minutes point out that the decision to implement the restructuring was “deferred pending further developments in the lawsuit regarding MARINOL®.” (*Id.* at BICJURIS0180) This sort of high-level reporting is within the normal range of information

on which a parent company would be updated. (Tab 98, 5/19/09 Macey Dep. 131 (noting that it is “standard practice for a parent corporation to monitor and oversee its subsidiaries’ operations” and “to set high level policy and strategy at a subsidiary.”)) Ultimately, however, it was the Roxane Board of Directors, not BIC’s Board, that approved the sale by entering unanimous written consents, approving the sale to Elan Pharma International, Limited. (Tab 42, Roxane Unanimous Consents at BOEH04600226-247, BOEH04600369)

82. From this point on, Roxane’s product line was almost exclusively generic and BIPI-based employees provided no more support for Roxane’s marketing or sales. (Tab 2, 10/31/08 Berkle Dep. at 229; Tab 1, 1/27/05 Berkle Dep. at 155)

United States’ Response: The United States does not dispute that following the September 2001 divestiture of the palliative care line, BIPI had less involvement with Roxane’s business. The paragraph is otherwise disputed, and is not supported by the cited authority.

BIC and BIPI’s Reply: The Government provides no support for its contention that BIPI-based employees provided any support for Roxane’s marketing and sales after Roxane divested the palliative care product line and transferred the HIV product line to BIPI in 2001. *See O’Brien v. Town of Agawam*, 440 F. Supp. 2d 3, 5 n.1 (D. Mass. 2006) (disregarding “purported statements of ‘fact’ not properly supported by citations to the record” in summary judgment pleadings as required by L.R. 56.1). BIC and BIPI’s statement of fact is thus deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

V. Testimony of Professor Jonathan R. Macey

83. Jonathan Macey is the Sam Harris Professor of Corporate Law, Corporate Finance, and Securities Law at the Yale Law School, and Professor in the Yale School of Management. He currently serves as Deputy Dean of the Yale Law School, and is a member of the Board of Directors of the Yale Law School Center for the Study of Corporate Governance and a Member of the Faculty Advisory Group of Yale’s Millstein Center for Corporate Governance Performance. Professor Macey has served on the boards of directors of numerous companies, has taught many joint business

and law school classes on corporate governance and business organizations, and has written extensively on those topics. (Tab 88, Macey Dep. Ex. 1 (Macey CV))

United States' Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

84. His areas of expertise are “corporate governance, corporate control, ordinary and standard business practices among, parent, subsidiaries and affiliate corporations, and economic and public policy related to corporate groups and relationships among parent, subsidiary and affiliate corporations.” (Tab 11, 5/19/09 Macey Dep. 45) He has studied, written and taught extensively on these topics. (Tab 88, Macey Ex. 1 (Macey CV))

United States' Response: Undisputed.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

85. Professor Macey analyzed the corporate governance issues related to the interactions and relationships between the BIC, BIPI and Roxane, including whether the companies “operated as separate and independent corporate entities” and whether the “relationships were consistent with ordinary and customary business practices” as well as sound public policy. (Tab 11, Macey Dep. 47-48) In the course of his work he looked at, among other information, the history of the companies, the relationships and interactions between the entities and how they evolved over time, the corporate formalities followed by the companies and the capitalization and financial condition of Roxane. (*Id.* 53-54)

United States' Response: The United States does not dispute that Professor Macey purports to offer opinions on whether BIC, BIPI and Roxane “operated as separate and independent corporate entities” and whether the relationships between the defendants “were consistent with ordinary and

customary business practices.” The United States disputes the materiality of any such conclusions, however, as Professor Macey’s testimony that the defendants are “separate and independent” entities is inadmissible opinion evidence. The issue of whether evidence is sufficient to pierce the corporate veil “is a question of law” and, in the First Circuit, piercing the corporate veil is appropriate “if one corporation is not an independent entity, but rather the mere alter ego of another.” *Brotherhood of Locomotive Engineers v. Springfield Terminal Ry. Co.*, 210 F.3d 18, 25 (1st Cir. 2000). Professor Macey’s testimony is squarely addressed to a legal conclusion, and therefore immaterial and inadmissible, as the First Circuit holds that “[i]t is not for witnesses to instruct the jury as to applicable principles of law, but for the judge.” See *Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92 (1st Cir. 1997) (citing *United States v. Newman*, 49 F.3d 1, 7 (1st Cir. 1995)). Moreover, whether or not the relationships among the defendants were consistent with “ordinary and customary business practices” or “sound public policy” is irrelevant to BIC or BIPI’s liability under the False Claims Act.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. See L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

BIC and BIPI dispute that Professor Macey’s testimony is “squarely addressed to a legal conclusion, and therefore immaterial and inadmissible.” Professor Macey does not offer an opinion as to whether Roxane and its affiliates are alter egos as a matter of law or whether BIC and/or BIPI should be held liable for Roxane’s actions as a matter of law. Professor Macey is not offering opinions about the ultimate conclusions of law, but is rather offering opinions about the relationships among Roxane, BIC, and BIPI. (Tab 98, 5/19/09 Macey Dep. 18, 126, 232-33) Thus, Professor Macey’s opinion provides a factual benchmark relevant to the legal determination, namely, whether the interactions between Roxane and its affiliates are unusual or eccentric. Normal and typical corporate behavior and functioning is not a matter of common sense for a lay person – it involves complex organization, myriad functions, and issues of efficiency and sound business practice that could be out of an ordinary juror’s grasp. See, e.g., *Cary Oil Co. v. MG Refining & Mktg., Inc.*, No.

99 Civ. 1725, 2003 WL 1878246, at *5-6 (S.D.N.Y. Apr. 11, 2003) (permitting expert witness to “offer a laymen jury the necessary information needed to understand basic issues of corporate governance” and veil piercing); *Pinal Creek Group v. Newmont Mining Corp.*, 352 F. Supp. 2d 1037, 1045 (D. Az. 2005) (permitting expert witness to “opine on corporate norms,” the relationship between two companies, “and how that relationship was consistent with, or diverged from, corporate norms.”). The Government’s assertion that Professor Macey’s testimony is not admissible is therefore incorrect.

Professor Macey’s testimony about whether “the relationships among the defendants were consistent with ‘ordinary and customary business practices’ or ‘sound public policy’” is also material. In order to hold BIC and BIPI liable under the False Claims Act on its veil-piercing claim, the Government must demonstrate that the relationships and connections among BIC, BIPI and Roxane were “uncommon” or “outside the norm” among corporate groups and at a level evidencing “pervasive control” by BIC or BIPI. *See, e.g., In re Acushnet River & New Bedford Harbor Proceedings*, 675 F. Supp. 22, 35 (D. Mass. 1987) (“[t]o the extent that Aerovox is integrated into or controlled by RTE, the relationship does not appear to be at a level uncommon between parent and wholly owned subsidiary.”); *In re Lupron Mktg. & Sales Practices Litig.*, 245 F. Supp. 2d 280, 292 (D. Mass. 2003) (“[t]he bulk of plaintiffs’ alter-ego theory is based on the customary incidents of a parent-subsidary relationship—ownership, common personnel, profits, and managerial oversight. These emblems are not suspect”); *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 604 F. Supp. 2d 325, 329 (D. Mass. 2009) (“[n]one of this evidence indicates that [the defendants] enjoyed anything other than the traditional parent-subsidary relationship established for purpose of limiting the parent’s liabilities and obligations.”).

86. Professor Macey’s opinion, based on “[his] research and practical experience in the area of corporate governance” is that “the relationship between BIC, as a parent holding company,

and Roxane was well within the normal range with respect to corporate governance relationships and corporate formalities and corporate separateness and maintaining an actual corporate identity . . . with respect to both of those entities.” On this same basis, Professor Macey’s opinion is that the corporate relationships between BIPI and BIC, and BIPI and Roxane, are normal and typical. (*Id.* 51-52)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

BIC and BIPI dispute that Professor Macey’s “opinions constitute inadmissible opinion evidence.” Professor Macey does not offer an opinion as to whether Roxane and its affiliates are alter egos as a matter of law or whether BIC and/or BIPI should be held liable for Roxane’s actions as a matter of law. Professor Macey is not offering opinions about the ultimate conclusions of law, but is rather offering opinions about the relationships among Roxane, BIC, and BIPI. (Tab 98, 5/19/09 Macey Dep. 18, 126, 232-33) Thus, Professor Macey’s opinion provides a factual benchmark relevant to the legal determination, namely, whether the interactions between Roxane and its affiliates are unusual or eccentric. Normal and typical corporate behavior and functioning is not a matter of common sense for a lay person – it involves complex organization, myriad functions, and issues of efficiency and sound business practice that could be out of an ordinary juror’s grasp. *See, e.g., Cary Oil Co.*, 2003 WL 1878246, at *5-6 (permitting expert witness to “offer a laymen jury the necessary information needed to understand basic issues of corporate governance” and veil piercing); *Pinal Creek Group*, 352 F. Supp. 2d at 1045 (permitting expert witness to “opine on

corporate norms,” the relationship between two companies, “and how that relationship was consistent with, or diverged from, corporate norms.”). The Government’s assertion that Professor Macey’s testimony is not admissible is therefore incorrect.

Professor Macey’s testimony is relevant to BIC and/or BIPI’s liability under the False Claims Act. In order to hold BIC and BIPI liable under the False Claims Act on their veil-piercing claim, the Government must demonstrate that the relationships and connections among BIC, BIPI and Roxane were “uncommon” or “outside the norm” among corporate groups and at a level evidencing “pervasive control” by BIC or BIPI. *See, e.g., In re Acushnet River*, 675 F. Supp. at 35 (“[t]o the extent that Aerovox is integrated into or controlled by RTE, the relationship does not appear to be at a level uncommon between parent and wholly owned subsidiary.”); *In re Lupron Mktg. & Sales Practices Litig.*, 245 F. Supp. 2d at 292 (“[t]he bulk of plaintiffs’ alter-ego theory is based on the customary incidents of a parent-subsidary relationship – ownership, common personnel, profits, and managerial oversight [t]hese emblems are not suspect”); *Am. Med. Sys., Inc.*, 604 F. Supp. 2d at 329 (“[n]one of this evidence indicates that [the defendants] enjoyed anything other than the traditional parent-subsidary relationship established for purpose of limiting the parent’s liabilities and obligations.”).

87. In reaching his opinion that the relationships among the defendants were normal and typical, Professor Macey’s methodology involved “comparing the actual interactions among these companies . . . with ordinary and customary business practice and . . . industry norm” and then looking at the “public policy benefits and costs associated with those” to determine whether the relationships among BIC, BIPI, and Roxane were “one, normal and consistent with . . . U.S. corporate practice, and two, whether they presented any . . . externality or cost or policy issues.” (*Id.* 54-55) According to Professor Macey, corporate relationships are considered normal and typical if “they are consistent with standard practice with what we observe other similarly situated, similarly organized corporations doing . . . [a]nd two, whether there are any kind of special problems associated with a particular form of or particular pattern of behavior among parents and subsidiaries or sibling corporations.” (*Id.* 55)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible

opinion evidence and/or are irrelevant to BIC or BIPI's liability under the False Claims Act. (*See supra* United States' Response to Paragraph 85)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

BIC and BIPI dispute that Professor Macey's opinions "constitute inadmissible opinion evidence." Professor Macey does not offer an opinion as to whether Roxane and its affiliates are alter egos as a matter of law or whether BIC and/or BIPI should be held liable for Roxane's actions as a matter of law. Professor Macey is not offering opinions about the ultimate conclusions of law, but is rather offering opinions about the relationships among Roxane, BIC, and BIPI. (Tab 98, 5/19/09 Macey Dep. 18, 126, 232-33) Thus, Professor Macey's opinion provides a factual benchmark relevant to the legal determination, namely, whether the interactions between Roxane and its affiliates are unusual or eccentric. Normal and typical corporate behavior and functioning is not a matter of common sense for a lay person – it involves complex organization, myriad functions, and issues of efficiency and sound business practice that could be out of an ordinary juror's grasp. *See, e.g., Cary Oil Co.*, 2003 WL 1878246, at *5-6 (permitting expert witness to "offer a laymen jury the necessary information needed to understand basic issues of corporate governance" and veil piercing); *Pinal Creek Group*, 352 F. Supp. 2d at 1045 (permitting expert witness to "opine on corporate norms," the relationship between two companies, "and how that relationship was consistent with, or diverged from, corporate norms.")). The Government's assertion that Professor Macey's testimony is not admissible is therefore incorrect.

Professor Macey's testimony is relevant to BIC and/or BIPI's liability under the False Claims Act. In order to hold BIC and BIPI liable under the False Claims Act on its veil-piercing claim, the Government must demonstrate that the relationships and connections among BIC, BIPI and Roxane were "uncommon" or "outside the norm" among corporate groups and at a level evidencing "pervasive control" by BIC or BIPI. *See, e.g., In re Acushnet River*, 675 F. Supp. at 35 ("[t]o the extent that Aerovox is integrated into or controlled by RTE, the relationship does not appear to be at a level uncommon between parent and wholly owned subsidiary."); *In re Lupron Mktg. & Sales Practices Litig.*, 245 F. Supp. 2d at 292 ("[t]he bulk of plaintiffs' alter-ego theory is based on the customary incidents of a parent-subsidary relationship – ownership, common personnel, profits, and managerial oversight. These emblems are not suspect"); *Am. Med. Sys., Inc.*, 604 F. Supp. 2d at 329 ("[n]one of this evidence indicates that [the defendants] enjoyed anything other than the traditional parent-subsidary relationship established for purpose of limiting the parent's liabilities and obligations.").

88. Professor Macey's basis for what constitutes a normal and typical corporate relationship is "what corporations actually do." Professor Macey testified "I study corporate relationships, I study corporate groups, and I study the interactions among these groups from a wide variety of perspectives and so it's a matter of my research and experience as to . . . what it is that we observe in . . . the landscape of U.S. business." (*Id.* 58-59)

United States' Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI's liability under the False Claims Act. (*See supra* United States' Response to Paragraph 85)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.").

BIC and BIPI dispute that Professor Macey's opinions "constitute inadmissible opinion evidence." Professor Macey does not offer an opinion as to whether Roxane and its affiliates are alter egos as a matter of law or whether BIC and/or BIPI should be held liable for Roxane's actions as a matter of law. Professor Macey is not offering opinions about the ultimate conclusions of law, but is rather offering opinions about the relationships among Roxane, BIC, and BIPI. (Tab 98, 5/19/09 Macey Dep. 18, 126, 232-33) Thus, Professor Macey's opinion provides a factual benchmark relevant to the legal determination, namely, whether the interactions between Roxane and its affiliates are unusual or eccentric. Normal and typical corporate behavior and functioning is not a matter of common sense for a lay person – it involves complex organization, myriad functions, and issues of efficiency and sound business practice that could be out of an ordinary juror's grasp. *See, e.g., Cary Oil Co.*, 2003 WL 1878246, at *5-6 (permitting expert witness to "offer a laymen jury the necessary information needed to understand basic issues of corporate governance" and veil piercing); *Pinal Creek Group*, 352 F. Supp. 2d at 1045 (permitting expert witness to "opine on corporate norms," the relationship between two companies, "and how that relationship was consistent with, or diverged from, corporate norms.")). The Government's assertion that Professor Macey's testimony is not admissible is therefore incorrect.

Professor Macey's testimony is relevant to BIC and/or BIPI's liability under the False Claims Act. In order to hold BIC and BIPI liable under the False Claims Act on its veil-piercing claim, the Government must demonstrate that the relationships and connections among BIC, BIPI and Roxane were "uncommon" or "outside the norm" among corporate groups and at a level evidencing "pervasive control" by BIC or BIPI. *See, e.g., In re Acushnet River*, 675 F. Supp. at 35 ("[t]o the extent that Aerovox is integrated into or controlled by RTE, the relationship does not appear to be at a level uncommon between parent and wholly owned subsidiary."); *In re Lupron Mktg. & Sales*

Practices Litig., 245 F. Supp. 2d at 292 (“[t]he bulk of plaintiffs’ alter-ego theory is based on the customary incidents of a parent-subsidary relationship – ownership, common personnel, profits, and managerial oversight. These emblems are not suspect”); *Am. Med. Sys., Inc.*, 604 F. Supp. 2d at 329 (“[n]one of this evidence indicates that [the defendants] enjoyed anything other than the traditional parent-subsidary relationship established for purpose of limiting the parent’s liabilities and obligations.”).

89. Professor Macey testified that it is normal and typical for holding companies, or one subsidiary in a corporate family – like BIPI – to provide shared services for the other subsidiaries, such as legal IT, financial and accounting services. (*Id.* 68-69)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85)

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

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not a matter of common sense for a lay person – it involves complex organization, myriad functions, and issues of efficiency and sound business practice that could be out of an ordinary juror’s grasp. *See, e.g., Cary Oil Co.*, 2003 WL 1878246, at *5-6 (permitting expert witness to “offer a laymen jury the necessary information needed to understand basic issues of corporate governance” and veil piercing); *Pinal Creek Group*, 352 F. Supp. 2d at 1045 (permitting expert witness to “opine on corporate norms,” the relationship between two companies, “and how that relationship was consistent with, or diverged from, corporate norms.”). The Government’s assertion that Professor Macey’s testimony is not admissible is therefore incorrect.

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90. Professor Macey also noted that it is “beyond routine . . . for personnel within subsidiaries to be actively involved in the management and operations of sibling companies because . . . it’s extremely common to see people in these various corporate groups wear a multitude of hats.” (*Id.* 74) It is also “extremely common for subsidiary companies to contract with each other and to

have interactions of a variety of kinds. . . .” (*Id.*) Both practices are common because it allows the “expertise of one . . . or the services of one” to be “utilized for the benefit” of another.” (*Id.* 74-75)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85)

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91. Based on this benchmark of typical corporate relationships, Professor Macey concluded that when a BIPI officer, Sheldon Berkle, held certain oversight responsibilities over certain Roxane products, “he wasn’t really doing anything by or on behalf of BIPI” and would not be characterized as a BIPI agent. (*Id.* 78-79) Professor Macey concluded that “he was wearing two hats and he was operating as a Roxane person.” (*Id.* 79)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85) In addition, Professor’s Macey testimony that Mr. Berkle “wasn’t really doing anything by or on behalf of BIPI” and “would not be characterized as a BIPI agent” lacks foundation. Determining whether an agency relationship exists is a multi-factored analysis properly left to the jury. *See Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570, 574 (1st Cir. 2004). Mr. Berkle himself testified that he never was an officer at Roxane and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.) at 53:1 - 53:18)

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

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Professor Macey’s testimony is relevant to BIC and/or BIPI’s liability under the False Claims Act. In order to hold BIC and BIPI liable under the False Claims Act on its veil-piercing claim, the

Government must demonstrate that the relationships and connections among BIC, BIPI and Roxane were “uncommon” or “outside the norm” among corporate groups and at a level evidencing “pervasive control” by BIC or BIPI. *See, e.g., In re Acushnet River*, 675 F. Supp. at 35 (“[t]o the extent that Aerovox is integrated into or controlled by RTE, the relationship does not appear to be at a level uncommon between parent and wholly owned subsidiary.”); *In re Lupron Mktg. & Sales Practices Litig.*, 245 F. Supp. 2d at 292 (“[t]he bulk of plaintiffs’ alter-ego theory is based on the customary incidents of a parent-subsidary relationship – ownership, common personnel, profits, and managerial oversight. These emblems are not suspect”); *Am. Med. Sys., Inc.*, 604 F. Supp. 2d at 329 (“[n]one of this evidence indicates that [the defendants] enjoyed anything other than the traditional parent-subsidary relationship established for purpose of limiting the parent’s liabilities and obligations.”). Professor Macey’s opinion is also relevant to the determination of whether Mr. Berkle had and was wearing a “Roxane hat” when he did work on behalf of Roxane such that his actions cannot be imputed to BIPI as a basis for direct liability under the False Claims Act.

BIC and BIPI dispute that Professor Macey’s testimony that Mr. Berkle “wasn’t really doing anything by or on behalf of BIPI” and “would not be characterized as a BIPI agent” lacks foundation. In support of his opinions, Professor Macey reviewed a significant amount of documentary and testimonial evidence, which he identified on his list of materials considered and discussed in detail at his deposition. (Tab 98, 5/19/09 Macey Dep. 22-25, 28-33) More specifically, he testified that he read the depositions of Messrs. Berkle, Duy, Russillo, Sykora, Tupa, Ciarelli, McIntyre, and Perri, and Ms. Paoletti and Waterer, and documents cited in the individual depositions. (*Id.* at 30-31, 33) He also described the type of information he looked for in those materials, including information related to the history of the companies and the relationships and interactions between the entities and how they evolved over time. (*See* BIC/BIPI SOF at ¶ 85) He

explained several times the analysis he used to determine whether someone was an agent from his perspective (Tab 98, 5/19/09 Macey Dep. 80-81, 161-62, 195-96) and described at least one specific piece of evidence, an employee bulletin, that he believed satisfied that analysis. (*Id.* at 92-93) Further, the Government had ample opportunity to cross-examine Professor Macey on his opinion.

The Government's citation to *Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570, 574 (1st Cir. 2004) for the proposition that "determining whether an agency relationship exists is a multi-factored analysis properly left to the jury" is incomplete and misleading. In *Camacho*, the court merely identified factors that "an inquiring court should consider" when "determining whether a hired party is an employee under the general common law of agency." *Id.* (quoting *Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 323 (1992)). Additionally, *Camacho* concerns issues of liability based on a determination of whether a de facto employer-employee relationship exists, and more specifically "whether harbor pilots, who lack a conventional employment relationship with the Authority, properly may be regarded as the [Puerto Rico Ports] Authority's employees for ADEA purposes." *Id.* at 573. Professor Macey did not testify that Mr. Berkle was a Roxane employee. Moreover, Professor Macey was not necessarily analyzing whether Mr. Berkle was an agent of Roxane "under the general common law of agency." *Id.* at 574. Rather, Professor Macey was using "the commonly held understanding" of the term "agent" and the concept of agency as recognized in business organizations. (Tab 98, 5/19/09 Macey Dep. 79, 162-63) More specifically, he was noting that Mr. Berkle held certain oversight responsibilities over certain Roxane products, and in that capacity, Mr. Berkle was wearing his "Roxane hat" and "was operating as a Roxane person." (*Id.* at 78-79)

The Government's additional facts and statements do not controvert BIC and BIPI's statement of fact. BIC and BIPI do not dispute that Mr. Berkle was not paid by, or an officer of,

Roxane, but dispute that his testimony is inconsistent with the fact that he wore a “Roxane hat” while performing certain tasks. (*Id.* at 74-76, 158-61) Professor Macey testified that in situations where employees serve dual roles at two companies, “the overwhelming business practice in the United States is to have people receive a single paycheck.” (Tab 99, 5/20/09 Macey Dep. 269-70) Professor Macey was “not aware of very many, if any, situations where a company would, while having somebody wear two hats go to the sort of, kind of extreme bureaucratic step . . . [to] pay them two different paychecks . . . it’s just inefficient to be paid by both and we don’t observe that in the way business is conducted.” (*Id.* at 270-71) He further testified that “there is absolutely no requirement in agency principles that the agent be compensated by the principal in the form of being an employee or kind of direct cash.” (Tab 98, 5/19/09 Macey Dep. 162) Moreover, Mr. Berkle served on the Roxane Board, was a Vice-President at BIC and was Head of the Business Unit Ethical Pharmaceuticals, which included Roxane. (Tab 90, 10/31/2008 Berkle Dep. 52-53; *see* BIC and BIPI’s Reply to SOF ¶ 7)

92. Professor Macey observed that the particular facts of this case made it “extremely easy to tell, for example, when Mr. Berkle is acting for Roxane and when Mr. Berkle is acting for BIPI”, because Roxane’s products were separate and distinct from BIPI’s drugs. As such, Mr. Berkle’s decisions regarding particular drugs would not apply to both companies. (*Id.* 81-82)

United States’ Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI’s liability under the False Claims Act. (*See supra* United States’ Response to Paragraph 85) In addition, Professor’s Macey testimony lacks foundation. Determining whether an agency relationship exists is a multi-factored analysis properly left to the jury. *See Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570, 574 (1st Cir. 2004). Mr. Berkle himself testified that he never was an officer at Roxane and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 15 (10/31/2008 Berkle Dep.) at 53:1 - 53:18)

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93. Professor Macey determined that certain BIPI employees who were given responsibilities with regard to Roxane's brand and branded generic products in 1998, “took on . . . a second hat” and “became agents of Roxane.” (*Id.* 159-161) To the extent that individuals such as Mr. Leonetti, Mr. Fulton, Mr. Ciarelli, and Mr. King were involved in the high level supervision of Roxane's brand and branded generic products, in that capacity, “they were acting as agents of Roxane.” (*Id.* 166-167) Professor Macey noted that “virtually without exception one observes these kind of dual relationships which involve somebody who is accepting one paycheck from one company, who is kind of seconded . . . or acting as an agent wearing a second hat with respect to a second company.” (*Id.* 167) Macey also testified that in those situations where employees serve dual roles at two companies, the “overwhelming business practice in the United States is to have people receive a single paycheck.” (Tab 12, 5/20/09 Macey Dep. 269- 270)

United States' Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, these opinions constitute inadmissible opinion evidence and/or are irrelevant to BIC or BIPI's liability under the False Claims Act. (*See supra* United States' Response to Paragraph 85) In addition, Professor's Macey testimony lacks foundation. Determining whether an agency relationship exists is a multi-factored analysis properly left to the jury. *See Camacho v. Puerto Rico Ports Authority*, 369 F.3d 570, 574 (1st Cir. 2004).

Moreover, Mr. King testified that although he supervised Roxane sales personnel, he was employed by BIPI for his entire career and was never paid by Roxane. (BIC/BIPI Fauci Exhibit 30 (12/3/2004 King Dep.) at 11:13 - 12:4, 15:2 - 15:23, 25:15 - 26:8) Similarly, Mr. Ciarelli testified that he was employed and paid by BIPI for his entire tenure with Boehringer Ingelheim. (BIC/BIPI Fauci Exhibit 51 (6/26/2002 Ciarelli Dep.) at 9:17 - 10:11, 50:6 - 50:13) Likewise, Mr. Leonetti worked for BIPI, and there is no evidence he was ever a Roxane agent or employee. (BIC/BIPI Fauci Exhibit 53 (1/27/2005 Berkle Dep.) at 219:19 - 220:7; BIC/BIPI Fauci Exhibit 54 (4/3/2003 Rowenhorst Dep.) at 125:15 - 126:6)

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Professor Macey’s testimony is relevant to BIC and/or BIPI’s liability under the False Claims Act. In order to hold BIC and BIPI liable under the False Claims Act on its veil-piercing claim, the

Government must demonstrate that the relationships and connections among BIC, BIPI and Roxane were “uncommon” or “outside the norm” among corporate groups and at a level evidencing “pervasive control” by BIC or BIPI. *See, e.g., In re Acushnet River*, 675 F. Supp. at 35 (“[t]o the extent that Aerovox is integrated into or controlled by RTE, the relationship does not appear to be at a level uncommon between parent and wholly owned subsidiary.”); *In re Lupron Mktg. & Sales Practices Litig.*, 245 F. Supp. 2d at 292 (“[t]he bulk of plaintiffs’ alter-ego theory is based on the customary incidents of a parent-subsidary relationship – ownership, common personnel, profits, and managerial oversight. These emblems are not suspect”); *Am. Med. Sys., Inc.*, 604 F. Supp. 2d at 329 (“[n]one of this evidence indicates that [the defendants] enjoyed anything other than the traditional parent-subsidary relationship established for purpose of limiting the parent’s liabilities and obligations.”). Professor Macey’s opinion is also relevant to the determination of whether certain BIPI employees with supervisory responsibility had and were wearing “Roxane hats” when they did work on behalf of Roxane such that their actions cannot be imputed to BIPI as a basis for direct liability under the False Claims Act.

BIC and BIPI dispute that Professor Macey’s testimony lacks foundation. In support of his opinions, Professor Macey reviewed a significant amount of documentary and testimonial evidence, which he identified on his list of materials considered and discussed in detail at his deposition. (Tab 98, 5/19/09 Macey Dep. 22-25, 28-33) More specifically, he testified that he read the depositions of Messrs. Berkle, Duy, Russillo, Sykora, Tupa, Ciarelli, McIntyre, and Perri, and Ms. Paoletti and Waterer, and documents cited in the individual depositions. (*Id.* at 30-31, 33) He also described the type of information he looked for in those materials, including information related to the history of the companies and the relationships and interactions between the entities and how they evolved over time. (*See* BIC/BIPI SOF at ¶ 85) He explained several times the analysis he used to

determine whether someone was an agent from his perspective (Tab 98, 5/19/09 Macey Dep. 80-81, 161-62, 195-96) and described at least one specific piece of evidence, a memo announcing a 1998 reorganization, that he believed satisfied that analysis. (*Id.* at 92-93) Further, the Government had ample opportunity to cross examine Professor Macey on his opinion.

The Government's citation to *Camacho*, 369 F.3d at 574 for the proposition that "determining whether an agency relationship exists is a multi-factored analysis properly left to the jury" is incomplete and misleading. In *Camacho*, the court merely identified factors that "an inquiring court should consider" when "determining whether a hired party is an employee under the general common law of agency." *Id.* (quoting *Nationwide Mut. Ins. Co.*, 503 U.S. at 323). Additionally, *Camacho* concerns issues of liability based on a determination of whether a de facto employer-employee relationship exists, and more specifically "whether harbor pilots, who lack a conventional employment relationship with the Authority, properly may be regarded as the [Puerto Rico Ports] Authority's employees for ADEA purposes"; Professor Macey did not testify that Messrs. King, Ciarelli or Leonetti were Roxane employees. *Id.* at 573. Moreover, Professor Macey was not necessarily analyzing whether they were agents of Roxane "under the general common law of agency." *Id.* at 574. Rather, Professor Macey was using "the commonly held understanding" of the term "agent" and the concept of agency as recognized in business organizations. (Tab 98, 5/19/09 Macey Dep. 79, 162-63) More specifically, he was noting that certain BIPI employees who were given responsibilities with regard to Roxane's brand and branded generic products in 1998, "took on . . . a second hat" and "became agents of Roxane." (*Id.* at 159-61)

The Government's additional facts and statements do not controvert BIC and BIPI's statement of fact. BIC and BIPI do not dispute that Mr. King testified that he supervised Roxane sales personnel and was employed by BIPI for his entire career. BIC and BIPI dispute the

Government's statement that Jim King testified that he was never paid by Roxane. This is not supported by the referenced testimony. BIC and BIPI do not dispute that Mr. Ciarelli testified that he was employed by BIPI and that "it says BIPI on [his] paycheck." (Tab 91, 6/26/02 Ciarelli Dep. 50) BIC and BIPI do not dispute that Mr. Leonetti worked for BIPI.

BIC and BIPI dispute that the testimony regarding Mr. King, Mr. Ciarelli, and Mr. Leonetti and their employment history controverts the facts set forth in BIC and BIPI's ¶ 93. Professor Macey testified that in situations where employees serve dual roles at two companies, the "overwhelming business practice in the United States is to have people receive a single paycheck." (Tab 99, 5/20/09 Macey Dep. 269-70) Professor Macey was "not aware of very many, if any, situations where a company would, while having somebody wear two hats go to the sort of, kind of extreme bureaucratic step . . . [to] pay them two different paychecks . . . it's just inefficient to be paid by both and we don't observe that in the way business is conducted." (*Id.* at 270-71) He further testified that "there is absolutely no requirement in agency principles that the agent be compensated by the principal in the form of being an employee or kind of direct cash." (Tab 98, 5/19/09 Macey Dep. 162)

94. Professor Macey testified that in some situations it could be difficult to tell which hat an employee is wearing at a given time, but here "we can tell on whose behalf these people are operating as agent because we know, we can see whose company's products they were involved with . . ." (Tab 11, 5/19/09 Macey Dep. 167-68)

United States' Response: The United States does not dispute that Professor Macey offered the opinions contained in this paragraph. Further answering, *see supra* United States' Responses to Paragraphs 85, 92, and 93.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 ("Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted

by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI incorporate their Replies to ¶¶ 85, 92 and 93.

95. Professor Macey also examined Roxane’s balance sheets and profit and loss statements to determine whether Roxane was adequately capitalized over time. (Tab 12, 5/20/09 Macey Dep. 297) Professor Macey has been qualified to serve as a member of a public corporation’s audit committee, and in that capacity, is responsible for reviewing the company’s financial statements and ensuring they are in accordance with appropriate accounting principles. (*Id.* 299) In this case, Professor Macey evaluated a number of different factors relevant to a company’s level of capitalization, such as whether there were incursions on Roxane’s initial capitalization and capital surplus, the amount of Roxane’s retained earnings, Roxane’s dividend policy, and Roxane’s average debt-to-equity ratio compared with average debt-to-equity ratios among other pharmaceutical firms. (*Id.* 318-20, 336-337). Professor Macey calculated Roxane’s average retained earnings between 1995 and 2005, and Roxane’s average dividend payments between 1995 and 2005. (*Id.* 338) Based on this analysis, Professor Macey concluded that Roxane was sufficiently capitalized during the relevant time period. (*Id.* 296, 311-312)

United States’ Response: The United States does not dispute that Professor Macey purports to offer an opinion that “Roxane was sufficiently capitalized during the relevant time period.” The United States disputes the materiality of this paragraph, however, as Professor Macey’s opinion lacks foundation. In addition, Roxane’s “average retained earnings” and its “average” dividend payments have no bearing on whether or not Roxane was adequately capitalized at any particular point in time, or is adequately capitalized now.

Further answering, Professor Macey did not compare Roxane’s level of capitalization to that of any other pharmaceutical companies. (BIC/BIPI Fauci Exhibit 61 (5/20/2009 Macey Dep.) at 320:2 - 320:6.) Instead, Professor Macey compared Roxane’s capitalization to “an industry benchmark,” under which Professor Macey claimed it was not unusual to see debt to equity ratios in the “5 to 1 to 10 to 1 range.” (*Id.* at 318:3 - 320:20). Professor Macey’s understanding of this benchmark is based only on his recollection of literature in the field. (*Id.*) From 1996 through 2001, Roxane’s equity consistently exceeded total liabilities; that is, Roxane’s liabilities to equity ratio was consistently *less than one to one*. (*See supra* in the United States’ Responses to Paragraphs 36 and 39) This is consistent with the level of capitalization observed at Roxane’s competitors. Specifically, four of the six Roxane competitors for which the United States was able to obtain financial data had liabilities to equity ratios of less than 1.5 to 1 throughout the time frame. (BIC/BIPI Fauci Exhibit 101 (Declaration of Patrick Ormond) ¶¶ 17-19)

Roxane’s liabilities to equity ratio grew to over 5 to 1 in 2002, following Roxane’s payment of a \$320 million dividend to BIC in November of that year. Payment of that dividend constituted a departure from Roxane’s past practices, and left Roxane significantly less capitalized than many of its competitors. Moreover, payment of the dividend apparently violated Boehringer Ingelheim’s own guidelines, which provide dividends are appropriate if a company’s debt to equity ratio is less than 1.5 to 1. (BIC/BIPI Fauci Exhibit 45 (2/26/2009 McIntyre Dep.) at 210:4 - 211:4). Following payment of the dividend, Roxane’s liabilities were over *fives times* greater than its total equity.

BIC and BIPI's Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”). BIC and BIPI object to the Government’s response to the extent it is based on the Declaration of Patrick Ormond, which was submitted after the close of discovery and with respect to which BIC and BIPI did not have the opportunity to conduct discovery.

BIC and BIPI dispute that Professors Macey’s testimony lacks foundation. The foundation for his testimony is set forth in ¶ 95. Furthermore, in support of his opinions, Professor Macey reviewed a significant amount of documentary and testimonial evidence, which he identified on his list of materials considered and discussed in detail at his deposition. (Tab 98, 5/19/09 Macey Dep. 22-25, 28-33)

BIC and BIPI dispute that “Roxane’s ‘average retained earnings’ and its ‘average’ dividend payments have no bearing on whether or not Roxane was adequately capitalized at any particular point in time, or is adequately capitalized now.” Professor Macey testified that he reviewed these factors to determine whether Roxane was adequately capitalized over time. (Tab 99, 5/20/09 Macey Dep. 297, 336-39) Thus, Roxane’s average retained earnings and average dividend payments are material as they establish Roxane’s overall solid financial position during the relevant timeframe and support that it was able to independently generate substantial income over time and had sufficient capital to meet its obligations.

BIC and BIPI further dispute that “Professor Macey did not compare Roxane’s level of capitalization to that of any other pharmaceutical companies.” On the contrary, Professor Macey testified that although he did not compare Roxane’s level of capitalization to “specific”

pharmaceutical companies, he did compare it to the “specific industry average.” (*Id.* at 320) BIC and BIPI do not dispute that Professor Macey compared Roxane’s capitalization to “an industry benchmark,” under which it was not unusual to see debt-to-equity ratios “in the 5-to-1 to 10-to-1 range.” (*Id.* at 318)

The Government’s additional facts regarding Roxane’s dividend payments and the relationship between Roxane’s liabilities and its equity and that of its competitors are incorrect, misleading and immaterial. These facts are immaterial to whether Roxane was adequately capitalized, as the record is replete with evidence showing that Roxane was adequately capitalized and able to meet its obligations as they came due, even after paying the \$320 million dividend. (BIC/BIPI SOF ¶¶ 37, 39-40; Tab 129, Pomer Declaration at ¶¶ 6, 16) Indeed, Roxane remains in business today and continues to generate income and meet its obligations. (Tab 129, Pomer Declaration at ¶ 16)

BIC and BIPI dispute any implication that the 2002 dividend payment was inappropriate or motivated by the Government’s 2000 subpoena. No evidence supports this implication; rather it is contradicted by the record evidence, which demonstrates that the amount and timing of the payment were based on legitimate business circumstances and reasons. (*See* BIC and BIPI’s Reply to SOF ¶ 36, which is incorporated in its entirety herein)

Moreover, BIC and BIPI dispute the Government’s statement that Roxane’s liabilities were over five times larger than its equity at the end of 2002 following the dividend payment because it is incorrect and misleading. The “total liabilities” figure that the Government uses includes short-term liabilities that should have been excluded and would have reduced the ratio calculated by the Government. (Tab 129, Pomer Declaration at ¶ 15; *see also* Tab 130, Steffen Decl. at ¶¶ 4, 9 (short-term liabilities should be excluded from debt-to-equity ratio)) Proposed Treasury Regulations

Section 1.163(j)-3 provides the IRS's definitions and computation guidelines for determining debt-to-equity ratios relevant to dividends. (*Id.*) Under those guidelines, short-term liabilities are excluded from the calculation. (*Id.*) Roxane's balance sheet as of December 2002 lists a significant number of short-term liabilities that Roxane would not have included in its debt-to-equity ratio calculation, including Trade Accounts Payable of \$17.7 million, Tax Provisions of \$15.3 million and Deferred Taxes of \$34.1 million. (*Id.*) Also, the Other Provisions and Accruals category, at \$59.7 million, likely contains a large portion of short-term obligations that would not be included in Roxane's debt-to-equity ratio calculations. (*Id.*)

BIC and BIPI also dispute that Roxane's 2002 dividend to BIC was inconsistent with Boehringer Ingelheim guidelines. The Government misinterprets the Boehringer Ingelheim guideline and uses the same incorrect debt-to-equity ratio computation described above. The Boehringer Ingelheim guideline applied to the U.S. subsidiaries on a consolidated basis, rather than to the individual debt-to-equity ratios of each subsidiary. (Tab 129, Pomer Declaration at ¶¶ 13-14) Therefore, a dividend was considered within guideline when the combined debt-to-equity ratio of the U.S. subsidiaries was less than 1.5 to 1. (*Id.*) In addition, for purposes of the dividend guideline, BIC and its subsidiaries calculate their debt-to-equity ratios based upon the Proposed Treasury Regulations Section 1.163(j)-3, which provides the IRS's definitions and computation guidelines for determining debt-to-equity ratio. (*Id.* at ¶ 15) Under those guidelines, short-term liabilities are excluded from the calculation. (*Id.*) As described above, Roxane's balance sheet as of December 2002 had a significant amount of short-term liabilities that would have been excluded for purposes of determining whether the consolidated ratio was within guideline.

Finally, BIC and BIPI dispute the Government's comparisons of Roxane's debt-to-equity ratio to those of its competitors as they are based on a flawed, unreliable and therefore irrelevant

“analysis” done by the auditor for the Department of Justice, Mr. Ormond. (See BIC and BIPI’s Reply to SOF ¶ 39; Tab 130, Steffen Declaration at ¶¶ 4-9) The significant flaws in Mr. Ormond’s analysis make it a wholly unreliable basis upon which to reach any conclusion regarding how Roxane’s debt-to-equity ratio compared to its competitors and does not create a genuine issue of fact regarding the adequacy of Roxane’s capital. (Tab 130, Steffen Declaration at ¶ 4) BIC and BIPI incorporate their Replies to ¶¶ 36-39.

96. Professor Macey’s opinion, based on the totality of the record, is that Roxane operated as an independent company. (Tab 11, 5/19/09 Macey Dep. 87-88) As a distinct corporate entity, Professor Macey determined that Roxane did “maintain operational control over its business” and that included “control over the pricing and marketing of its products.” (*Id.* 122-123)

United States’ Response: The United States does not dispute that Professor Macey purports to offer an opinion that Roxane “operated as an independent company.” The United States disputes the materiality of this paragraph, however, as Professor Macey’s testimony that the defendants are “separate and independent” entities is inadmissible opinion evidence. The issue of whether evidence is sufficient to pierce the corporate veil “is a question of law” and, in the First Circuit, piercing the [sic] corporate veil is appropriate “if one corporation is not an independent entity, but rather the mere alter ego of another.” *Brotherhood of Locomotive Engineers v. Springfield Terminal Ry. Co.*, 210 F.3d 18, 25 (1st Cir. 2000). Therefore, Professor Macey’s testimony is squarely addressed to a legal conclusion, and the First Circuit holds that “[i]t is not for witnesses to instruct the jury as to applicable principles of law, but for the judge.” *See Nieves-Villanueva v. Soto-Rivera*, 133 F.3d 92 (1st Cir. 1997) (*citing United States v. Newman*, 49 F.3d 1, 7 (1st Cir. 1995)). Further answering, *see infra* United States’ Responses to Paragraphs 85, 92 and 93.

BIC and BIPI’s Reply: The Government does not dispute the substance of this statement of fact, and thus it is deemed admitted. *See* L.R. 56.1 (“Material facts of record set forth in the statement required to be served by the moving party will be deemed for purposes of the motion to be admitted by opposing parties unless controverted by the statement required to be served by opposing parties.”).

BIC and BIPI dispute that Professor Macey’s opinions “constitute inadmissible opinion evidence.” Professor Macey does not offer an opinion as to whether Roxane and its affiliates are alter egos as a matter of law or whether BIC and/or BIPI should be held liable for Roxane’s actions

as a matter of law. Professor Macey is not offering opinions about the ultimate conclusions of law, but is rather offering opinions about the relationships among Roxane, BIC, and BIPI. (Tab 98, 5/19/09 Macey Dep. 18, 126, 232-33) Thus, Professor Macey's opinion provides a factual benchmark relevant to the legal determination, namely, whether the interactions between Roxane and its affiliates are unusual or eccentric. Normal and typical corporate behavior and functioning is not a matter of common sense for a lay person—it involves complex organization, myriad functions, and issues of efficiency and sound business practice that could be out of an ordinary juror's grasp. *See, e.g., Cary Oil Co.*, 2003 WL 1878246, at *5-6 (permitting expert witness to “offer a laymen jury the necessary information needed to understand basic issues of corporate governance” and veil piercing); *Pinal Creek Group*, 352 F. Supp. 2d at 1045 (permitting expert witness to “opine on corporate norms,” the relationship between two companies, “and how that relationship was consistent with, or diverged from, corporate norms.”). The Government's assertion that Professor Macey's testimony is not admissible is therefore incorrect.

BIC and BIPI incorporate their Replies to ¶¶ 85, 92 and 93.

Dated: September 22, 2009

Respectfully submitted,

/s/ John W. Reale
 Helen E. Witt, P.C.
 Anne M. Sidrys, P.C.
 Eric T. Gortner
 John W. Reale
 KIRKLAND & ELLIS LLP
 300 North LaSalle Street
 Chicago, IL 60654
 Telephone: (312) 862-2000
 Facsimile: (312) 862-2200
Counsel for Defendants
Boehringer Ingelheim Corp. and
Boehringer Ingelheim Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on September 22, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale